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## RISK FACTORS

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*An investment in our H Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before making an investment in our H Shares. Particularly, we are a biotech company [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. 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 and results of operations. In any such case, the market price of our H Shares could decline, and you may lose all or part of your investment given the nature of biotech industry.*

*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 will not be updated after the date hereof, and is subject to the cautionary statements in “Forward-looking Statements” in this document.*

We believe there are certain risks and uncertainties involved in an investment in our H Shares, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to the development of our drug candidates; (ii) risks relating to the manufacturing and commercialization of our drug candidates; (iii) risks relating to our financial position and need for additional capital; (iv) risks relating to extensive government regulation; (v) risks relating to our intellectual property rights; (vi) risks relating to our operations; (vii) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or that we currently deem immaterial could also harm our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

### **RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES**

*Our drug candidates will be subject to intense competition with biologic drugs and other drugs for autoimmune and allergic diseases after commercialization and may fail to compete effectively against competitors.*

The pharmaceutical industry is subject to intense competition. In particular, according to Frost & Sullivan, competition within China’s biologic drug market for autoimmune and allergic diseases is expected to continue to intensify in the following years, primarily due to growing efforts among pharmaceutical companies to address the vast underserved medical needs in the field, favorable government policies and expansion of approved biologic drugs and indications. As a result, we will face intense competition with respect to any drug candidates that we may seek to develop or commercialize in the future.

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Many of our drug candidates will face competition from biologic drugs developed by major international and domestic pharmaceutical companies with the same targets as ours. For example, QX001S, our most advanced and only biosimilar drug candidate, is a proposed biosimilar to ustekinumab, one of the major biologic treatments and best-selling drugs for the treatment of Ps worldwide. If and when we obtain regulatory approval for QX001S, it will compete not only with the originator drug, Stelara, but also with other biosimilars of ustekinumab and biologics of the same target in China. As of the Latest Practicable Date, Stelara had been approved for the treatment of Ps in China and three other biologic drug candidates with the same target as QX001S were in the clinical stage. In particular, we expect QX001S to face intense competition upon its commercialization considering that the other two ustekinumab biosimilar candidates in China commenced their Phase III clinical trials at a similar time as our Phase III trial. Similarly, we also expect our Core Products, QX002N and QX005N, to face (i) intense competition from approved drugs from multinational pharmaceutical companies, such as secukinumab and ixekizumab for QX002N and dupilumab for QX005N; and (ii) potential competition from drug candidates under clinical development in China. Specifically, as of the Latest Practicable Date, there were 10 IL-17-targeting biologic drug candidates in addition to QX002N indicated for AS in the clinical stage in China and 20 biologic drug candidates in addition to QX005N for AD in the clinical stage in China, among which 9 were IL-4R $\alpha$  inhibitors. Some of the drug candidates in the clinical stage were in the same or a more advanced stage of development than our QX002N or QX005N.

The ability of our drug candidates to successfully compete with other drugs of the same targets and gain market share against the originator drug and other biosimilars will depend on various factors, including the timing of regulatory approval, the efficacy and safety profile of our drug candidates in comparison to other drugs, convenience of our dosing regimens, pricing and market coverage of our or our commercialization partner’s sales and distribution channels. However, we cannot guarantee you that we will be able to successfully compete on all or any of the aforementioned aspects against major pharmaceutical companies that operate on a global or national level, which may have stronger medical and technological capabilities, greater pricing flexibility, better track records, greater brand name recognition or greater financial, marketing and public relations resources than we do.

Furthermore, our drug candidates will also face competition from biologic drugs with different targets developed for the same indication. For example, in addition to IL12/IL23 inhibitors, QX001S will also compete with, among others, TNF- $\alpha$  inhibitors and IL-17A inhibitors which are or will be approved by the NMPA for the treatment of Ps in China. In addition, traditional non-biologic medications are widely prescribed for autoimmune and allergic disease in China. We cannot guarantee you that biologic drugs will successfully replace these traditional therapies for the relevant patient population. Furthermore, newer generations of drugs, including biologics and small-molecule targeted drugs, may be developed that compete with our drugs. For example, tyrosine kinase 2 (TYK2) inhibitors, a newer family of small-molecule targeted drugs, have demonstrated in clinical studies promising efficacy profiles and improvements on traditional limitations of JAK-related toxicities. These newer-generation drugs may have advantages such as ease of administration.

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If any or all of our drug candidates fail to compete effectively in one or more of the aforementioned fronts, our competitors may be able to establish a strong market position and render our drug candidates non-competitive or even obsolete before we can recover the expenses of developing and commercializing any of our drug candidates. Our efforts to compete may compel us to reduce prices for our drug, or take other measures that may adversely affect our profitability. Such inability to compete effectively could erode our profit margins and market share, which may in turn materially and adversely affect our business, financial position, results of operations and growth potential.

***We depend substantially on the success of our drug candidates, all of which are undergoing preclinical or clinical development. If we are unable to successfully complete clinical development of our drug candidates, or experience significant delays in doing so, our business prospects will be significantly impacted.***

Our business will depend on the successful development of our existing drug candidates and new drug candidates that we may identify and develop. As of the Latest Practicable Date, our pipeline consisted of eight drug candidates in various phases of preclinical or clinical development and we had one drug candidate, QX001S, at the BLA filing stage in China. We cannot guarantee you that we can successfully complete the preclinical and clinical development of any of our existing drug candidates in a timely manner, or at all. Most of our drug candidates will require further preclinical and/or clinical development before they could obtain regulatory approval in China and potentially other jurisdictions.

All of our drug candidates are biologic drugs indicated for the treatment of autoimmune or allergic diseases. The development for such drugs is a complex and challenging process due to various factors, including but not limited to: (i) complicated mechanisms of autoimmune and allergic diseases, which are multifactorial disorders that may involve dysregulated immune responses, genetic and environmental factors and interactions between different cell types and signaling pathways; (ii) limited understanding of the relevant pathogenesis despite significant advances in the research of autoimmune and allergic diseases in recent years; (iii) heterogeneous patient populations with varying symptoms, disease severity and responses to a specific therapy; (iv) complex standards for drug evaluation, which requires the use of multiple endpoints, including clinical, biochemical, and immunological measures; and (v) safety concerns, including infections, allergic reactions, and immune-related toxicities. Therefore, the development of biological drugs for autoimmune and allergic diseases is a complex and challenging process that requires a deep understanding of disease pathogenesis, careful selection of patient populations and rigorous evaluation of drug safety and efficacy.

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We have invested a significant portion of our efforts and financial resources in the discovery and development of our drug candidates. For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our research and development expenses amounted to RMB151.9 million, RMB257.2 million and RMB263.3 million, respectively. We expect to continue to incur substantial and increasing expenditures through the projected commercialization of our drug candidates. The success of our drug candidates in terms of preclinical or clinical development will depend on a number of factors, including:

- successful completion of preclinical studies;
- receipt of regulatory approvals for our clinical trials;
- successful enrollment of patients in, and completion of, clinical trials;
- favorable safety and efficacy data from our clinical trials and other studies;
- maintaining sufficient manufacturing capabilities to ensure supply of our drug candidates for clinical use;
- our ability to effectively and simultaneously design, manage and supervise a significant number and range of clinical trials;
- our ability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to negotiation and may vary among different CROs and trial sites;
- the performance by CROs, or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- our ability to control clinical trial-related costs;
- our ability to obtain sufficient supplies of competitor drugs or originator drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity; and
- ensuring that we do not infringe upon, misappropriate or otherwise violate the patents, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties against us on these fronts;

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays in completing or be unable to complete the preclinical or clinical development of our drug candidates, resulting in our inability to obtain regulatory approval for

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our drug candidate. As a result, we may fail to generate sufficient revenue or cash flow from product sales to continue our operations, in which event our financial condition, results of operations and business prospects will be materially and adversely affected.

***Clinical development of our drug candidates involves a lengthy and expensive process with uncertain outcomes, and the results of preclinical studies and clinical trials may not be indicative of the final results.***

Clinical trials are expensive, difficult to design and implement, and may take years to complete. At the same time, their outcomes are inherently uncertain. Failure can occur at any time during clinical development. Moreover, the results of preclinical studies and early-stage clinical trials may not be indicative of the results of later clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired outcomes in safety and efficacy in spite of having progressed through the earlier stages of clinical trials. In some instances, there can be significant variability in the safety and/or efficacy results among different trials of the same drug candidates due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the subject pools, such as genetic differences, patient compliance with the dosing regimen and other trial protocol elements, and the rate of dropout among clinical trial participants. We cannot guarantee that our future clinical trial results will be favorable based on the current available preclinical and clinical data.

As a result, we may not be able to control the timing and expenses related to completing our clinical trials or obtaining regulatory approval. Unfavorable clinical trial results may force us to restructure our clinical trials, increase our drug development cost and delay our receipt of regulatory approval for our drug candidates. Therefore, it may take us longer to begin commercializing our drug candidates and navigate the path to profitability, while other companies who are developing drugs for the same indications may be able to gain a competitive advantage if they commercialize their drugs first, potentially affecting our ability to gain market share and acceptance, which may have a material adverse effect on our business, financial position and our results of operations.

***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 be subject to unfavorable circumstances during the development and commercialization of our drug candidates.***

Before obtaining regulatory approval for the commercial sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates for their proposed indications. Results of our clinical trials could reveal limited efficacy or unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and the NMPA may order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications.

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Even if we could obtain regulatory approval for our drug candidates, in the event that the results of our clinical trials are only modestly positive, or if they raise safety concerns regarding our drug candidates, we may still be subject to unfavorable circumstances, including:

- obtain approval for indications that are not as broad as intended;
- be required to market our drugs under more restrictive labels, such as adding additional warnings and cautionary statements;
- be required to suspend the sales and marketing of our drugs if they had been approved and commercialized;
- be subject to additional post-marketing testing requirements;
- be held liable for harm caused to our patients and be subject to litigation and product liability claims; and
- be unable to obtain adequate insurance coverage or reimbursement for our drugs from the government or commercial insurers.

If we experience any of the above undesirable conditions, our business may be materially harmed, and we may not be able to generate sufficient revenues and cash flows to continue our operations and may experience a decline in the market price of our H Shares.

***We may encounter difficulties in enrolling subjects in our clinical trials, which may delay our clinical development activities or lead to higher development costs for our drug candidates.***

The timely completion of clinical trials depends on, among others, our ability to enroll a sufficient number of subjects who will remain in the clinical trials until their conclusion. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects, or if there are delays in the enrollment of eligible subjects. We may encounter challenges with enrolling subjects in our clinical trials for various reasons beyond our control, such as:

- difficulties with recruiting a sufficient number of subjects that possess the traits and characteristics we seek;
- the subjects' perceptions as to the potential advantages and risks of the drug candidates being studied in relation to other available drugs or drug candidates;
- the resources we have to facilitate timely subject enrollment in our clinical trials;
- the efforts made by trial executing personnel, including our CROs, to screen and recruit eligible subjects; and
- the proximity and availability of clinical trial sites for prospective subjects.

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Our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates. This competition will reduce the number and types of patients available to us as some patients might choose to enroll in a trial being conducted by one of our competitors instead of ours.

Even if we are able to enroll a sufficient number of patients in our clinical trials, patient enrollment may also be delayed as a result of public events, epidemics or similar incidences which are out of our control, such as the COVID-19 pandemic. During the Track Record Period, COVID-19 outbreak caused delays in our ongoing clinical trials for various drug candidates. Such delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent timely completion of these trials and adversely affect our ability to advance the development, regulatory approval and commercialization of our drug candidates.

***We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.***

We may rely on third-party organizations, such as CROs, hospitals and clinics, to monitor, support and execute preclinical studies and/or clinical trials for our drug candidates. In 2021, 2022 and the nine months ended September 30, 2023, we engaged 28, 37 and 31 CROs, respectively. In particular, We engaged CROs to conduct preclinical PK, PD and toxicity studies and all completed and ongoing clinical trials of both QX002N and QX005N. We have limited control over the operations of such third parties, and may have less control over the timing, quality and cost of the relevant preclinical and clinical studies than if we conducted these studies by ourselves. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

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 preclinical programs. Our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates if (i) CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines; (ii) they need to be replaced; or (iii) the quality or accuracy of the clinical data that they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols and regulatory requirements. For example, the third parties on which we rely to execute our preclinical studies are required to conduct such studies in accordance with the good laboratory practice (GLP) and the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》). We, our CROs and our clinical investigators are also required to comply with the good clinical practice (GCP), which are regulations and guidelines enforced by the NMPA and other relevant authorities, during the clinical development of our drug candidates. Our pivotal

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clinical trials must be conducted with products produced in accordance with the cGMP standards. If any of our CROs or clinical investigators fail to comply with these regulations, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or other regulatory authorities may require us to perform additional or repeat clinical trials before approving our marketing applications, which would delay the regulatory approval process.

Furthermore, if any of our relationships with our third-party CROs is terminated, we may not be able to enter into arrangements with alternative CROs in a timely manner or on commercially reasonable terms, if at all, and we may not be able to meet our desired clinical development timelines. Even if we could successfully replace the original CROs in a timely manner, it is possible that the type and quality of services the new CROs provide do not conform to our original standards. Replacing or engaging new CROs could be time-consuming and expensive and may divert management’s time and focus. To the extent that we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter any challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

*The data we gather in our research and development may be affected by factors unrelated to our drug candidates or out of our control, which could adversely affect the reliability of our clinical results or analyses.*

We collect, aggregate, process and analyze data when we identify a promising drug candidate and while conducting preclinical studies and clinical trials. During the process, the overall quality of data collected or accessed may be affected by many factors that are unrelated to the tested drug candidates and out of our control. For example, we cannot assure the trial subjects’ full compliance with the trial protocols. Additionally, we cannot guarantee that all of our employees or staff of our CROs would strictly comply with the good clinical practice (GCP) standards or other related guidelines and regulations when collecting or accessing preclinical and/or clinical data. We may not be able to discover every data issue and error when monitoring and auditing our data.

Such factors may negatively affect the reliability of our trial results and analyses and the NMPA or other regulatory authorities may require us to perform additional or repeat clinical trials before approving our marketing applications. Major issues in data integrity could also subject us to questions or claims from the NMPA or other relevant authorities, and may expose us to liability relating to our storage, handling, submission, delivery or display of clinical data. Although we maintain insurance coverage for clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. Any such claims or proceedings brought against us may negatively impact our business, prospects and reputation.



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***We may not be able to discover or develop suitable novel drug candidates.***

We plan to continue building our pipeline through our internal discovery and development platforms by identifying new therapeutic targets and drug candidates and pursuing the development of our drug candidates for additional indications. During the process, we may require additional technical, financial or other resources to enhance our existing research and development capabilities.

The successful discovery of new therapeutic targets or drug candidates depend, to a large extent, on factors out of our control, such as the emergence of new scientific methodologies in the medical industry, initial safety and efficacy results of potential candidates and the availability of technical, financial or other resources to support our discovery effort. We cannot assure you that we will ever be able to identify additional therapeutic opportunities for our drug candidates or develop suitable potential drug candidates through internal research programs, any of which could materially and adversely affect our future growth and prospects. Even if we do identify initially promising drug candidates, there is no guarantee that we will obtain favorable results in later clinical development of such candidates. Failure to successfully identify or develop novel and suitable drug candidates may materially and adversely affect our ability to expand our pipeline and grow our business.

***We may not be successful in adapting to new technologies and methodologies.***

Our continued competitiveness depends on our ability to adapt to evolving technological developments and methodologies in the biotech and pharmaceutical industry. However, adapting to the latest technological developments and methodologies may require us to invest significant resources to enhance our own research and development, testing and manufacturing capabilities. There is no assurance that we will be able to secure such resources, or that we will succeed in making the necessary improvements. We also cannot guarantee that we will be successful in our attempts to adapt our drug candidates to emerging technologies and methodologies in a way that will gain market acceptance. Should we fail to respond in a timely or effective manner, we may be unable to improve and maintain our competitive position and materially and adversely affect our business and prospects.

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### RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

*We have no track record in commercializing our drug candidates. Our collaboration with pharmaceutical companies to market our drug candidate and our plan to establish an indication-specialized in-house commercialization team may not materialize as we expected.*

We do not have any track record of successfully launching and commercializing drugs. We intend to seek opportunities of strategic cooperation with well-known pharmaceutical companies with extensive experience in the sales and marketing of drugs for autoimmune and allergic diseases in China. For example, in August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. For details, see “Business—Collaboration with Zhongmei Huadong” in this document.

We believe collaboration with pharmaceutical companies such as Zhongmei Huadong will enable us to leverage their market access and sales and marketing network targeting the autoimmune or allergic diseases to execute our commercialization strategy for future approved drugs. However, there is no assurance that we will be able to establish or maintain such collaborative arrangements or, even if we are able to do so, that such arrangements will facilitate the commercialization of our drugs as expected. Once we enter into such collaboration agreements, the sales and marketing of our drugs will depend, to varying degrees, on the efforts of our partners, over whom we have limited influence or control and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. Collaborations involving our drug candidates are subject to various risks, for further discussion, see “—Risks Relating to Our Operations—We have entered into collaborations agreements, and may form or seek other collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.”

We also intend to build an indication-specialized in-house commercialization team, beginning with indications with relatively limited patient populations treated in a small number of key hospitals. However, establishing an in-house sales and marketing team requires significant expenditures, management resources and time. We would potentially have to compete with other drug companies to recruit, hire, train and retain marketing and sales personnel. Additionally, given the relatively small scale of our future in-house team, we cannot guarantee that we will succeed in establishing sufficient sales coverage and penetration to hospitals, pharmacies and other medical institutions across China, which could adversely affect the commercial opportunities of our drug candidates.

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*We may face extra obstacles in the commercialization of our biosimilar drug candidate, due to the uncertainty in approval pathway for biosimilars in China and heightened risks relating to potential patent litigation.*

The approval pathway for biosimilars in China remains fluid, which may adversely affect the regulatory approval of our biosimilar drug candidate. The NMPA issued the Technical Guideline for the Research, Development and Evaluation of Biosimilars (Tentative) (the “Biosimilars Guideline”) on February 28, 2015. The Biosimilars Guideline outlines the regulatory framework for biosimilars, aiming to move toward a clear industry structure for the development of biosimilars. On June 29, 2020, the NMPA issued the Requirements for Registration Classification and Application Dossiers of Biological Products (the “Registration Requirements”), which specifies Class 3.3 as the registration classification for biosimilars. However, various uncertainties surrounding the application and interpretation of the Biosimilars Guideline and the Registration Requirements could adversely affect the regulatory approval of our existing biosimilar drug candidate, namely, QX001S, our most advanced drug candidate. Uncertainties surrounding the approval process for biosimilars in China include:

- both the Biosimilars Guideline and the Registration Requirements remained unclear on certain fundamental issues for the administration of biosimilars, such as the evaluation criteria for interchangeability with reference products;
- although the Biosimilars Guideline adopted a stepwise comparability approach, it does not contain sufficient details to be regarded as overarching guidelines and it is also not clear whether the NMPA will take further steps to develop product-specific guidelines;
- while under the Registration Requirements biosimilars are subject to a separate approval pathway under Class 3.3, it remains unclear if the time to market for biosimilars will be reduced compared with the lengthy review process for innovative biologics; and
- the regulatory policies and guidelines may change in the future, and it is unpredictable whether the NMPA and other regulatory authorities will issue updated policies or guidelines to replace or supplement the Biosimilar Guidelines, or whether such updated policies or guidelines will bring additional compliance costs or substantial impediments for our biosimilar candidates to obtain regulatory approvals.

Additionally, biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which may delay or prevent the commercial launch of a drug candidate. Many pharmaceutical companies, including the ones that developed the reference drugs for which we are developing biosimilars, have developed worldwide patent portfolios of varying sizes and breadth. Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructions, vectors, growth media, production processes and purification processes. Not all such patents

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have expired globally, including potentially in the jurisdictions where we intend to commercialize our biosimilar drug candidate. Relevant parties may submit applications for patent term extensions in jurisdictions where extensions are available, seeking to extend patent protection. If approved, such extension may interfere with or delay the launch of our biosimilar product. As such, we cannot assure you that our QX001S will be approved under the Biosimilars Guideline, in a timely manner or at all, and we may not ultimately be able to develop and market it successfully if we are subject to related intellectual property infringement or misappropriation claims.

*Our drug candidates may fail to achieve market acceptance and commercial success.*

Even if we receive the requisite regulatory approvals for our drug candidates, there is no guarantee that our drug candidates will gain sufficient market acceptance across the medical community and among patients. The degree of market acceptance of our drug candidates will depend on, among other things, the following factors:

- the clinical indications for which our drugs are approved and patient demand for the drugs that treat those clinical indications;
- the potential and perceived advantages of our drugs over alternative treatments, including as to cost, effectiveness, safety and convenience;
- the time required to manufacture and launch our drugs, and to make them publicly available;
- the availability of adequate insurance coverage and reimbursement by the government and emerging commercial insurers;
- the willingness and ability of patients to pay out of pocket without the above-mentioned insurance coverage and reimbursement;
- reliance on and preference for current therapies by physicians, healthcare providers and clinics, and patients;
- drugs commercialized by our competitors, particularly if they are launched before, at or around the same time as our own drugs;
- the prevalence and severity of any side effects;
- labeling requirements imposed by the NMPA or other relevant authorities, particularly in relation to warnings as to health and safety risks or limitations on effectiveness;
- the effectiveness of our and our commercialization partner's sales and marketing efforts;

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- adverse publicity about our drugs or favorable publicity about competitive products; and
- potential product liability claims.

Additionally, biologic therapies have relatively limited track record in the treatment of autoimmune and allergic diseases in China, and extensive market education will be needed for the marketing our future approved drugs. We cannot assure you that such education efforts will generate sufficient acceptance for our drug candidates among patients with autoimmune and allergic diseases. Even if our drugs achieve market acceptance, we may not be able to maintain such market acceptance if new drugs or treatments that are more favorably received or cost effective than ours are introduced. Failure to achieve or maintain market acceptance of our drugs could adversely affect our business, prospects and results of operations.

*We have no track record in manufacturing drugs for commercial sale.*

We currently produce drug candidates for clinical use at our manufacturing facility in Taizhou and intend to manufacture drugs for future commercial sales at the same facility once our drug candidates obtain regulatory approval. We have no proven track record in manufacturing biologics for commercial sale. The manufacturing of biologic drugs is highly exacting and complex, due in part to strict regulatory requirements and medical and other scientific specifications. Should problems arise in the course of producing our drug candidates, we may need to dispose of batches and incur additional unexpected expenses in connection with replacement and disposal. Such incidents could, among other things, lead to increase in manufacturing costs and decline in our profit margin. We may also need to invest additional time and human resources to investigate the causes of the problems and formulate appropriate solutions. In cases where problems are discovered after our drugs reach the market, we may also be forced to issue recalls and be subjected to product liability claims.

Other challenges we may face during manufacturing include, but are not limited to:

- inability to obtain or maintain requisite approval to utilize manufacturing premises and/or operate manufacturing facilities;
- inability to procure consumables and/or raw materials of sufficient quantity and satisfactory quality in a timely manner, or at all;
- shortage of qualified manufacturing, quality control or quality assurance personnel to carry out and oversee the manufacturing process in accordance with relevant regulations;
- longer than expected periods of time necessary to commence or ramp up production; and
- delay in our development or approval timeline, which could lead to delay in our manufacturing schedule and low utilization rate of our manufacturing facilities.

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Secondary to our own manufacturing needs, we are also providing CDMO services to third parties through our manufacturing facility in Taizhou, which may lead to additional risks in the manufacturing process, such as inability to manufacture multiple biologic drugs in the same production line while conforming to applicable manufacturing standards, or failure to obtain sufficient numbers of orders to efficiently utilize our full manufacturing capacity and achieve economies of scale.

In the event that we encounter such issues, there is no guarantee that we will be able to timely or effectively resolve them. Given our limited experience with manufacturing biologics for commercial sale, we may be less adept at handling manufacturing issues or managing our manufacturing operations than our competitors. Additionally, should factors beyond our control affect our manufacturing processes such that we are unable to achieve or maintain cGMP or other required standards, regulators may issue warnings, withdraw regulatory approvals or take other actions such as recalls, seizures, totally or partially suspend our production, suspend ongoing clinical trials, refuse to approve pending applications or supplemental applications, halt production and distribution or impose civil and criminal penalties.

Furthermore, due to the complex nature of our drugs, we may not be able to manufacture them in a timely manner, at a price or in sufficient quantities necessary to be profitable. As our drug portfolio grows and matures, we will also need to expand our commercial manufacturing capacity in parallel. However, doing so may require significant capital expenditures and time. Failure to expand in a timely and cost-effective manner may affect our ability to manufacture sufficient quantities of drugs for sale and drug candidates for our development purposes. Should we be unable to maintain the efficiency of our manufacturing procedures or control our manufacturing costs, we may experience material adverse effects on our prospects, business and results of operations.

***Scarcity of available raw materials or increases in our raw material costs may negatively impact our business, financial condition and results of operations.***

We procure raw materials from both domestic and overseas suppliers according to our drug development plans. For certain raw materials with limited number of suppliers, should our suppliers temporarily suspend production, raise or be forced to raise their prices, or fail to supply such raw materials to us for other reasons such as logistical issues, we cannot guarantee that we will be able to find alternative suppliers who can provide the required raw materials and product components on reasonable terms, at sufficient amounts or in accordance with our desired quality standards in a timely manner, or at all. Certain raw materials necessary for the development and manufacturing our drug candidates are provided by third-party suppliers that are based outside of China, in which case they may need to maintain export or import licenses to continue providing us with required raw materials. We have no control over whether they will obtain and maintain, or be able to obtain and maintain, such export and import licenses or other permits and approvals necessary for their operations.

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Furthermore, we expect that our need for stable supply of raw materials will grow as we continue to expand our business and begin manufacturing drugs for commercial sale after we obtain regulatory approval. As more drug candidates progress into advanced stages of clinical trials, we will also require larger amounts of comparison drugs. Any significant delay in obtaining such raw materials or comparison drugs in the quantity and quality required may delay our preclinical studies and clinical trials, the regulatory approval for our drug candidates or the manufacturing of our future approved drugs.

Raw materials used in our manufacturing may be subject to price volatility caused by external conditions, such as fluctuations in transportation costs, changes in government policies and natural disasters. As a result, our raw materials costs may also fluctuate from time to time or increase substantially going forward, which could adversely affect our profitability. The search for replacement for our suppliers or raw materials may result in reduction in production volume and delay in our manufacturing, sales and marketing or other business operations, and may divert management attention and financial resources so as to materially and adversely affect our business, financial condition, results of operations and prospects.

***Failure to maintain effective quality control over our drugs, particularly undetected errors or defects in our manufacturing, may harm our reputation or expose us to product liability claims.***

The effectiveness of our quality control procedures depends on various factors, such as the procedures governing our manufacturing processes, the quality and reliability of our manufacturing facility and equipment, the qualification and experience of our manufacturing and quality control staff and our ability to ensure that the relevant personnel adhere to our quality control procedures. However, we cannot assure you that our internal policies and procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure of our quality control procedures could render our drugs unsuitable for use, adversely affect our ability to comply with applicable cGMP requirements, jeopardize our manufacturing permits and/or harm our market reputation and relationship with business partners. Any such events may have a material adverse effect on our business, financial condition and results of operations.

***Guidelines, recommendations and studies published by various organizations may disfavor our drug 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 demand for our drugs candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to drugs offered by our competitors, could diminish demand for our drug candidates and adversely impact our future sales revenues. Furthermore, the sales of our future approved drugs depends in part on our ability to educate patients and members of the medical community

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(including healthcare providers) about our drugs and drug candidates. Our ability to convey our messages effectively may be negatively impacted by the publication of guidelines, recommendations or studies on our drug candidates.

***There may be fewer market opportunities for our drug candidates than we originally anticipated, and our drug candidates may be ultimately unprofitable even if commercialized.***

We estimate the extent of market opportunities for our drug candidates by analyzing information from various third-party sources, such as scientific literature and industry reports. We also use such estimates to make decisions regarding our drug development strategies, including whether or not to prioritize the development of a particular drug candidate. However, these estimates may be based on imprecise or inaccurate data, leading us to over- or under-estimate market opportunities for certain drugs, which will affect our resource allocation decisions.

The market opportunities available will depend on, among others, the degree of acceptance for our drugs by the medical community, patient access, drug pricing and availability of government or commercial insurance and reimbursement. From time to time, we may discover that demand for our drugs is lower than anticipated due to the smaller-than-expected target patient population, availability of other more effective or accessible therapies and difficulty in identifying or approaching new patients. Such unfavorable developments may materially and adversely affect our prospects, business and results of operations.

***Medical insurance coverage and reimbursement may be limited or unavailable in certain market segments for our drugs, which may adversely affect their sales prospects.***

Successful sales of our future approved drugs partly depend on the availability of adequate insurance coverage and reimbursement from the government and commercial insurers, as patients often rely on such reimbursement for all or part of the costs associated with their medical treatment. Government authorities and commercial medical insurance providers will decide on the coverage of drugs and the amount of reimbursement, based on their consideration of factors such as:

- whether the drug and/or treatment is safe, effective and medically necessary;
- whether the drug and/or treatment is appropriate for specific diseases and/or patients;
- whether the drug and/or treatment is considered experimental or investigational; and
- whether the drug and/or treatment is cost-effective given their budgets or profit margins.



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We cannot guarantee that reimbursement will be available for our future approved drugs and, if available, the level of reimbursement. In China, the amounts reimbursable to program participants for their drug purchases depend on the inclusion of the drugs in the NRDL or other government-sponsored medical insurance programs, as well as the tiers under which the drugs are classified in such programs. The Ministry of Human Resources and Social Security (MOHRSS) of the PRC, the National Healthcare Security Administration (NHSA), together with provincial or local human resources and social security authorities, regularly review the inclusion of or removal of drugs from the NRDL, as well as the tier under which a drug will be classified. Even though the number of innovative drugs included in the NRDL is expected to increase in the future, there can be no assurance that any of our future approved drugs will be included in the NRDL or other government-sponsored medical insurance programs.

***Even if reimbursement is available, we may need to significantly concede on prices for our future approved drugs in China, which could adversely affect our profitability.***

For any of our future approved drugs seeking inclusion into the NRDL, we may need to engage in price negotiation with the NHSA or other relevant regulatory authorities, which may lead to a reduction in our prices. Even if the NHSA or any of its local counterparts includes any of our future approved drugs in the NRDL or the PRDL, which may increase the demand for such drugs, our potential revenue or profitability from the sales of such drugs may still decrease as a result of lowered prices. Additionally, eligibility for reimbursement in China does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution expenses.

Moreover, the prices we may offer to the NHSA and its local counterparts may be used as benchmarks and further reduced by discounts required by private hospitals. The centralized tender process in China may also create pricing pressure among substitute products or products that are perceived to be substitute products, and we cannot assure you that our future approved drugs would not be adversely affected.

***We may explore opportunities to commercialize our drugs globally, which may expose us to risks associated with conducting business in international markets.***

As we grow our business, we intend to cooperate with MNCs or pharmaceutical companies with established local sales networks to conduct clinical trials and/or sell our drugs outside of China. Should we succeed in doing so, our business is subject to risks associated with doing business globally, including (i) changes in a country or region’s political and cultural climate or general economic conditions, (ii) unexpected changes in or high costs associated with complying with laws and regulatory requirements, (iii) difficulties with enforcing contractual provisions in unfamiliar jurisdictions, (iv) potential disputes with foreign partners that may be protracted or more difficult to resolve due to distance and time differences, (v) exposure to litigation or third-party product liability claims outside of China, (vi) concerns voiced by local governments and regulators on arrangements pertaining to our research and clinical trial sites, (vii) inadequate intellectual property protection in other countries, (viii) the possibility of economic sanctions, trade restrictions, discrimination,

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protectionism or unfavorable policies against foreign drug companies, including those from China, (ix) the effects of applicable local tax regimes, royalties and other payment obligations owed to local governments, and (x) fluctuations in local currency exchange rates. Any of such occurrences could negatively affect our expansion plan.

*Our operation may be adversely affected by changes in the relationship between China and other nations.*

Changes in the political relationship between China and other nations may adversely affect various aspects of our business operation. For example, there have been significant uncertainties over the past few years about the relationship between the United States and China with respect to a range of important issues. It is unclear whether these uncertainties could be resolved effectively. They may continue to escalate going forward and result in certain types of goods, such as advanced R&D and manufacturing equipment and raw materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, if we decide to explore opportunities to conduct clinical trials and/or seek regulatory approval for our drug candidates in the U.S., such undesirable changes in the relationship between China and the U.S. may adversely affect our expansion plan, including our ability to effectively engage local service providers or collaboration partners and our prospect of receiving fair treatment from relevant regulatory authorities. Therefore, tensions and political concerns between China and other nations may therefore adversely affect our business, financial conditions, results of operations and prospects.

### **RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL**

*We have incurred significant operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future and may never become profitable. As a result, you may lose all or part of your investment in us.*

We are a pre-revenue biotech company and have not successfully commercialized any drug candidates. Investments in the development of innovative drugs such as ours are highly speculative. It entails substantial upfront capital expenditure and significant risks that a drug candidate may fail to gain regulatory approval or become commercially viable. As a result, you may lose all or part of your investment in us given the high risks involved in our business and associated with the biotech industry. During the Track Record Period, we did not generate any revenue from our drug candidates under development, and we will continue to incur significant research and development and other expenses related to our ongoing operations. Our ability to generate revenue will depend primarily on the success of the clinical trials, regulatory approval and commercialization of our drug candidates, which is subject to significant uncertainty. Even if we successfully complete clinical trials and obtain regulatory approval to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed applications of our approved drugs, and our ability to achieve sufficient market acceptance.

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We have incurred significant expenses related to the research and development of our drug candidates in the past. For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our research and development expenses amounted to RMB151.9 million, RMB257.2 million and RMB263.3 million, respectively, which contributed significantly to our net losses of RMB426.5 million, RMB312.3 million and RMB385.5 million in the same periods, respectively.

We expect to continue to incur net losses in the near future, and the losses may increase as we further our research and development efforts, seek regulatory approvals for our drug candidates and expand our collaboration with third parties for the commercialization of future approved drugs. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of manufacturing and commercializing any approved drugs and our ability to generate revenues.

We may never become profitable. Even if we achieve profitability in the future, we may not be able to maintain profitability in subsequent periods. Our failure to become or remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our R&D efforts, expand our business and/or continue our operations. Failure to become or remain profitable may adversely affect the market price of our H Shares. A decline in the market price of our H Shares could cause you to lose all or part of your investments in our business.

***We had net operating cash outflows during the Track Record Period and we may need to obtain additional financing to fund our operations.***

We recorded net cash outflow from operating activities of RMB122.6 million, RMB225.2 million and RMB252.2 million for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. We cannot assure you that we will be able to generate cash flows from operating activities in the future. Net operating cash outflow may impair our ability to make necessary capital expenditures and meet our liquidity requirements, thereby constraining our operational flexibility. If we are unable to maintain adequate working capital, we may default in our payment obligations and may not be able to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, our existing cash and cash equivalents may not be sufficient to enable us to complete all development or commercially launch all of our current pipeline products for the anticipated characteristics and to invest in additional programs. Accordingly, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that the financing may be available when we need them, on terms that are favorable to us, or at all.

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***Fair value changes in our wealth management products and related valuation uncertainty due to the use of unobservable inputs may adversely affect our financial condition and results of operations.***

During the Track Record Period, we acquired certain wealth management products to improve the utilization of our cash on hand on a short-term basis. We classified these wealth management products as financial assets at fair value through profit or loss (“FVTPL”). As of December 31, 2021 and 2022 and September 30, 2023, we recorded financial assets at FVTPL of RMB402.4 million, RMB401.1 million and RMB150.4 million, respectively. We recorded net realized and unrealized gains on financial assets at FVTPL of RMB6.5 million, RMB11.9 million and RMB4.6 million for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. However, we may incur fair value losses on such financial assets in the future, which will adversely affect our financial condition and results of operations.

Additionally, the fair value of these financial assets was established using significant unobservable inputs, including the expected interest return rate, which cannot be supported by observable market prices or rates and may involve management judgment and be inherently uncertain. See note 28(e) in the Accountants’ Report set out in Appendix I to this document for details. Any change in the judgment or the use of unobservable inputs may lead to different valuation results and, in turn, changes in the fair value of these financial assets and may adversely affect our financial condition and results of operations.

***We may need to obtain substantial additional financing to fund our operations and may be forced to accept unfavorable terms or limitations on our operation during the process. If financing is not available on terms acceptable to us, or at all, we may be unable to complete the development and commercialization of our drug candidates.***

We need to make substantial investments to complete preclinical and clinical development, obtain regulatory approvals, manufacture sufficient quantities of drug candidates for clinical and future commercial use and coordinate marketing activities in relation to our drug candidates as a condition to generating revenue. We also envisage significant funds to be expended on our post-approval commitments such as monitoring the efficacy and safety of our drugs on the market, if and when they are approved and commercialized. In doing so, we must expend substantial financial resources to fund our continuing and future operations.

During the Track Record Period, we funded our operations primarily through equity financing and the construction of our manufacturing facility primarily through bank borrowings. We may continue to rely on such methods, as well as debt financing, collaboration and licensing arrangements or other sources to raise additional capital. If we resort to other financing activities, we will incur financing costs and we cannot guarantee you that the financing may be available when we need them, on terms that are favorable to us, or at all. In the event 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

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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.

Furthermore, our ability to raise funds will also depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funding is not available to us on a timely manner, we may have to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or the manufacturing and commercialization for one or more of our drug candidates, which in turn will adversely affect our business prospects.

***The discontinuation of any government grants or preferential tax treatment currently available to us may adversely affect our business, financial condition and results of operations.***

We benefited from government grants and preferential tax treatment during the Track Record Period. We recorded government grants of RMB20.0 million, RMB9.2 million and RMB4.3 million for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. Such government grants primarily included subsidies to encourage research and development activities, subsidy for interest expenses of bank loans, reimbursement for capital expenditure incurred for the construction of our manufacturing facility and subsidies for talent recruitment. Additionally, Our Company obtained the certificate of high-technology enterprise in November 2021 and is subject to a preferential income tax rate of 15% for a three-year period. We also enjoyed deductible allowances for our research and development expenses during the Track Record Period.

We cannot assure you that we will continue to receive government grants or preferential tax treatment at the existing levels, or at all. The relevant authorities may issue administrative decisions or modify government policies that reduce the amount of government grants and preferential tax treatment that has been available to us, or end our eligibility to receive such financial subsidies. The discontinuation of government grants or preferential tax treatment currently available to us may adversely affect our results of operations and prospects. Further, prospective investors should note that should there be any changes in the amounts of our government grants and preferential tax treatment in a given year, our financial performance for that period may not be directly comparable to our historical financial results.

***We may be subject to penalties from the PBOC or adverse judicial rulings as a result of providing loan financings.***

In January 2021, we provided a short-term loan of RMB100.0 million to Taizhou Huawei Investment Ltd. (泰州華威投資有限公司) (“Taizhou Huawei”) with an expected yield at 7.0% per annum. The loan was fully settled in July 2021. We derived an interest income of RMB3.6 million from providing the loan in 2021. For further details, please refer to “Financial Information—Material Transactions with Related Parties” in this document.

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According to the General Lending Provisions (貸款通則) promulgated by the PBOC, only financial institutions may legally engage in the business of extending loans, and loans between companies that are not financial institutions are prohibited. The PBOC may impose a fine of one to five times of the income generated (being interests charged) from the loan advancing activities between enterprises. By providing the loan to Taizhou Huawei, we recognized an interest income of RMB3.6 million. Therefore, we may be subject to penalties by PBOC of up to RMB18.0 million under a strict reading of the General Lending Provisions. However, according to the Provisions of the Supreme People’s Court on Several Issues concerning the Application of Law in the Trial of Private Lending Cases (最高人民法院關於審理民間借貸案件適用法律若干問題的規定) (the “Private Lending Interpretations”), which became effective on September 1, 2015 and was latest amended on December 29, 2020, the Supreme People’s Court recognizes the validity and legality of financing arrangements and lending transactions between non-financial institutions so long as certain requirements, such as the interest rates charged, are satisfied and there is no violation of relevant provisions of laws and regulations.

As of the Latest Practicable Date, no administrative action, fine or penalty had been imposed by the PBOC on us regarding the loan. As advised by our PRC Legal Advisors, under the Private Lending Interpretations, PRC courts will support a company’s claim for interest from the date of engagement of contract to August 19, 2020 with relevant judicial interpretation at the time. PRC courts will also support such claim from August 20, 2020 to the date of repayment of the loan as long as (i) the annual interest rate does not exceed four times the prime rate for one-year loans published by the National Interbank Funding Center when the related lawsuit is brought; and (ii) the lending contract is valid under the PRC Civil Code and satisfies certain requirements of the Private Lending Interpretations. Based on the above, our PRC Legal Advisors is of the view that the risk that we would be subject to any penalty with respect to such interest-bearing loan pursuant to the General Lending Provisions by the relevant regulatory authorities is remote. However, the final determination of the relevant regulatory authorities could be different, and we may be subject to penalties from the PBOC or adverse judicial rulings as a result of our provision of loan financing to Taizhou Huawei Investment Ltd. during the Track Record Period or any prior periods. Any of these penalties or adverse judicial rulings could have a material adverse effect on our business, financial position and results of operations.

***We have incurred and may continue to incur share-based payments. The issuance of share-based payment awards may cause dilution to our existing Shareholders and may affect the market price of our H Shares.***

For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, we recognized equity-settled share-based payment expenses of RMB11.7 million, RMB41.6 million and RMB99.5 million, respectively. We only granted shares to our certain key employees during the Track Record Period. In the future, we may issue options and shares to our Directors, senior management and/or key employees to incentivize their performance and align their interests with ours. As a result, we may incur equity-settled share-based

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payments, which could have a material adverse effect on our net profits. Furthermore, the grant of equity-accounted share-based payments may result in an immediate and potentially substantial dilution to our existing Shareholders and could result in a decline in the value of our H Shares.

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

We are a biotech company with a relatively short operating history. Our operations to date have focused on business planning, raising capital, establishing our drug portfolio and conducting clinical trials of our drug candidates. Most of our drug candidates were still at various stages of development and we had not commercialized any of our drug candidates as of the Latest Practicable Date. Our limited operating history, particularly in the rapidly evolving pharmaceutical industry, may make it difficult to evaluate our current business and reliably predict our future performance. Our future financial performance will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. 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. These risks may cause potential investors to lose substantially all of their investment in us.

### **RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATION**

*The drug industry in China is highly regulated and such regulations are subject to change, which may adversely affect multiple aspects of our operation.*

We conduct our research, development and commercialization activities in China, which regulate such activities in great depth and detail. Biotech companies in China are subject to comprehensive government regulation and supervision encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development, approval, manufacturing, sales and marketing or post-approval approval process, may subject an applicant to administrative or judicial sanctions. These sanctions could include a regulator’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The failure to comply with these regulations could have a material adverse effect on our business, financial condition and prospects.

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In recent years, the regulatory framework in China regarding the drug industry has undergone significant changes, and we expect that it will continue to evolve. Any such changes may increase compliance costs related to our business, cause delays in or prevent the successful development or commercialization of our drug candidates and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC governmental authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our third-party contractors to maintain compliance with applicable laws and regulations may materially and adversely affect our business activities.

***The process of obtaining regulatory approval for our drug candidates is lengthy, expensive and inherently uncertain.***

The process required to obtain approval from the NMPA or other relevant authorities is a lengthy, expensive and uncertain process, and approval is never guaranteed. When we submit a registration application to the regulatory authorities, the regulatory authorities will decide whether to accept or reject the registration application. We cannot be certain that all of our submissions will be accepted for filing and review by the regulatory authorities. In addition, the time required to obtain approval from the regulatory authorities is unpredictable and could take years following the commencement of preclinical studies and clinical trials. Results of such applications depend upon numerous factors and are subject to substantial discretion of the regulatory authorities. As of the Latest Practicable Date, we had not received marketing approval for any of our drug candidates, and it is possible that none of our drug candidates or any drug candidates we may discover and seek to develop in the future will ever obtain such approval.

Our drug candidates could fail to obtain regulatory approval for many reasons, including uncertainties associated with, or as a result of, our clinical trials results and procedures. See “—Risks Relating to the Development of Our Drug Candidates—We depend substantially on the success of our drug candidates, all of which are undergoing preclinical or clinical development. If we are unable to successfully complete clinical development of our drug candidates, or experience significant delays in doing so, our business prospects will be significantly impacted.” However, even if we successfully complete all preclinical studies and clinical trials for our drug candidates in compliance with the current regulations of the NMPA or other relevant authorities, we may still face risks of failure to obtain regulatory approval due to factors beyond our control, such as changes in approval policies or regulations that render our preclinical and clinical data insufficient or require us to amend our clinical trial protocols, regulatory requests for additional analysis, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other drugs. Any of these occurrences may materially and adversely affect our approval and commercialization timeline and therefore harm our business, financial condition and prospects significantly.



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***Our failure to maintain or renew our drug manufacturing license, or other licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.***

Pursuant to relevant laws and regulations, we are required to obtain and maintain various licenses, permits and certificates from relevant authorities to operate our business. For example, Cellularforce, our CMC-focused subsidiary, holds the Drug Manufacturing Certificate (藥品生產許可證) issued by Jiangsu Medical Products Administration, which is necessary for the operation of our manufacturing facility in Taizhou, Jiangsu. Some of these licenses, permits and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities suspending our operations, and corrective measures requiring capital expenditure or remedial actions, which in the future 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 laws or regulations come into effect, requiring us to obtain any additional licenses, permits and certificates that were previously not required to operate our existing businesses, we cannot assure you that we will successfully obtain such licenses, permits and certificates. Our failure to obtain the additional licenses, permits and certificates may restrict the conduct of our business, decrease our revenues and/or increase our costs, which could materially reduce our profitability and prospects.

***Even after obtaining regulatory approval for marketing, our drug candidates will continue to remain subject to ongoing or additional regulatory requirements and review, which may result in significant additional expenses, or penalties if we fail to comply with such requirements.***

Once approved, our drugs may be subject to ongoing or additional regulatory requirements related to manufacturing, labeling, packaging, storing, advertising, promoting, sampling, record-keeping, post-marketing clinical trials and submission of information related to safety, efficacy and other post-marketing clinical data.

Drug manufacturers are required to comply with rules promulgated by the NMPA to ensure that quality control and manufacturing procedures conform to current good manufacturing practices (cGMP) regulations. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made to regulatory authorities, such as in any NDA or BLA, marketing applications or responses to queries and observations from relevant authorities. We expect to expend considerable time and resources to meet our various regulatory compliance obligations in relation to manufacturing, production and quality control.

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Furthermore, the regulatory approvals we may obtain for our drug candidates may be subject to conditions that affect the commercial potential of our drugs, or require that we conduct costly post-marketing clinical trials or other measures to monitor their safety and efficacy. The NMPA may also require us to follow a risk evaluation and mitigation program. Such conditions and requirements may lead to substantial increase in our compliance costs and any failure to comply with such conditions and requirements may cause the regulatory authorities to impose sanctions or penalties that could adversely affect our business operations.

*We may be subject to applicable anti-kickback, false claims, physician payment transparency, fraud and abuse or similar healthcare laws and regulations in China, which could, in the event of noncompliance, expose us to sanctions, penalties, contractual damages, reputational harm and diminished profits and future earnings.*

If we begin commercializing our drugs in China, our operations would be subject to various anti-kickback, false claims, medical staff payment transparency, fraud and abuse laws or similar healthcare laws and regulations in China, including, without limitation, the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and the PRC Drug Administration Law (《中華人民共和國藥品管理法》). These laws and regulations may impact, among other things, our proposed sales and marketing programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

Although we have put in place policies and procedures that ensure that we and our employees comply with fraud and abuse and other healthcare laws and regulations, we cannot guarantee that our employees, as well as third parties that we collaborate with such as CROs, hospitals, physicians and other medical professionals will fully comply with such laws and regulations at all times. In the event that our employees or other third party collaborators do not adhere to fraud and abuse and other healthcare laws and regulations, we may be subject to investigations, civil, criminal and administrative penalties and contractual damages that generate negative publicity and substantially harm our reputation, business and prospects.

*Off-label use of our products after their approval could lead to adverse drug reactions and negative results that may materially harm the reputation of our company and of the relevant drugs, while off-label use of our competitor drugs could adversely affect the market potential for our products, which in turn could affect our 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 have not been approved by the relevant authorities. Considering that many pathogenic pathways and therapeutical targets could apply to multiple indications within the field of autoimmune and allergic diseases, there remains the risk that our drug candidates and the drugs and drug candidates of our competitors could be subject to off-label drug use after obtaining

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regulatory approval and are prescribed for indications or in dosages or dosage forms that have not been approved by competent authorities, even though the NMPA and other relevant authorities actively enforce the laws and regulations prohibiting the promotion of off-label use.

On the one hand, in off-label use, our drug candidates may be less effective or entirely ineffective in the unintended patient population and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm the reputation of our company and of the relevant drugs, our commercial operations and our financial condition. These occurrences may also expose us to product liability claims, 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. On the other hand, off-label use of our competitor drugs could in effect intensify the competition that our products face and result in unlawful erosion of our market share, which could also adversely affect our business prospects.

### **RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS**

*If we are unable to obtain and maintain patent protection for our drug candidates, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and the commercial prospects of our drug candidates would be materially and adversely affected.*

We view the proprietary protection of our drugs as integral to our entire operation. Throughout the Track Record Period, we sought to protect the drug candidates and technologies that we consider commercially important by filing patent applications in China, the United States and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. Any failure by us to obtain or maintain patent protection with respect to our drug candidates and technologies could materially adversely affect our business, financial condition, results of operations and prospects.

The patent application and prosecution processes are expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner in all desirable territories. For example, in China, the China National Intellectual Property Administration (CNIPA) may require us to amend our patent applications after substantive examinations, including reducing the patentable coverage, and if we fail to respond within a specified period, our applications will be deemed to be withdrawn. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories. Furthermore, the patent positions of biotech and pharmaceutical companies are generally highly uncertain, involve complex legal and factual questions, and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain.

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Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. For example, in making any patent application, there is no guarantee that we will have been the first to develop our drug candidates or other proprietary technologies through independent means. In such cases, it is possible that our patent applications will be rejected. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection.

In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in certain jurisdictions are typically not published until 18 months after filing, or in some cases, not 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.

Furthermore, China and the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met and no objection are raised by other parties. Under the first-to-file system, if third parties file first, they may be granted a patent relating to a technology which we invented. In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA for confidential examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

***The scope of patent protection is uncertain and our current or any future patents may be challenged and invalidated even after issuance, which would materially and adversely affect our ability to successfully commercialize any drug candidates.***

The scope of patent protection in various jurisdictions is uncertain. Changes in patent laws or their interpretation in China or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our innovations, affect the value of our intellectual property, jeopardize ongoing patent applications and/or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing, and may pursue going forward, will be granted, or, if granted, whether they could continue to provide sufficient protection from competitors.

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 currently own or may own in the future are granted as patents, they may not be issued in

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a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, circumvented or invalidated by third parties.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other countries. An adverse determination from such challenges 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 without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Such challenges also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Furthermore, there is no guarantee that we will be granted patent extensions. On October 17, 2020, the Patent Law of the PRC was amended with effect from June 1, 2021, according to which the patent administration department under the State Council may, upon request, extend terms for invention patents relating to new drugs that have obtained regulatory approvals for no more than five years, and the total term of the patent right may not exceed 14 years after the regulatory approval for the marketing of a new drug. Similarly in the United States, we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting an NDA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of approval, only one patent may be extended, and only those claims covering the approved drug, a method for use, or a method for manufacturing may be extended. Following the expiration of our patents, it is possible that our competitors may develop and market generic version of such drugs, thereby materially and adversely affecting our ability to compete.

***Our drugs may become subject to intellectual property infringement or misappropriation claims or other legal challenges and such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.***

Our commercial prospect depends partly upon our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. Many drug companies maintain worldwide patent portfolios. Their patents may cover various aspects of a single drug, including but not limited to composition, administration method, cell line constructions, vectors, growth media, manufacturing processes and purification measures. Such patents may be valid globally, including in jurisdictions where we intend to commercialize our drugs. As the drug industry

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continues to expand and more patents are applied for and granted, we are subject to higher risks of unknowingly violating the patents of third parties. Furthermore, our competitors may also obtain patents that restrict or preclude our ability to lawfully manufacture and market our drugs.

We cannot guarantee that our drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. 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 that cover our drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our drug candidates or their use.

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, use or manufacture of the biologics we have developed or are developing. Such third parties might resort to litigation against us. Any patent or trademark infringement, trade secret misappropriation or other intellectual property claims or legal proceedings brought against us could result in substantial costs and divert capital resources and management attention. In the event that we are unsuccessful in defending such claims or legal proceedings, we may be compelled to accept one or more of the following solutions:

- pay substantial damages, court costs, and attorneys’ fees;
- obtain licenses or pay ongoing royalties on unfavorable terms;
- cease developing, manufacturing or selling drugs that incorporate the intellectual property in dispute;
- cease using and registering certain domain names, brands or trademarks in connection with some or all of our drugs and business activities in some or all jurisdictions in which we operate;
- redesign or reengineer drugs; and
- change our business processes.

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 ultimately prevail, or settle at an early stage, such litigation could burden us with substantial unanticipated costs.

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As the legal threshold for bringing intellectual property claims and proceedings against us is low, we may be subject to intellectual property claims and proceedings regardless of the merit and probability of success of such claims. Any intellectual property–related disputes or litigation, regardless of outcome or merit, could result in substantial costs and expenses, negative publicity and diversion of management resources. During the course of any intellectual property claims or proceedings, 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 as negative, the perceived value of our drug candidates, future drug candidates, programs or intellectual property could be diminished. Accordingly, the market price of our H Shares may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liability or require us to seek licenses that may not be available on commercially acceptable terms, if at all, which could have a material adverse effect on our business.

*We may face challenges associated with protecting our intellectual property rights in other jurisdictions.*

As of the Latest Practicable Date, we held 37 patents in China as well as 9 patents overseas. As of the same date, we also had 44 patent applications pending in China and overseas.

In the event that we are able to commercialize our drugs on an international scale, we may face challenges associated with protecting our intellectual property rights in other jurisdictions. Filing, prosecuting, maintaining and defending patents in all other countries throughout the world requires significant financial resources and management attention. Moreover, our intellectual property rights in other jurisdictions may be of different scope and strength as compared to those in our target markets. Consequently, we may not be able to entirely prevent third parties from using our intellectual property to produce, sell or import drugs in other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs, and may also export otherwise infringing drugs to jurisdictions where we do not have patent protection or strong patent enforcement rights. Such occurrences may diminish our competitive advantages, prospects and market share.

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

As intellectual property rights have limitations, they do not necessarily protect us from all potential threats in our competition with other biotech companies. Some of such limitations include:

- others may be able to manufacture drugs that are similar to our drug candidates or apply similar technology that is not covered by the patents we own or license, now or in the future;
- others may independently develop similar drugs through methods or means that do not technically infringe, misappropriate or otherwise violate our intellectual property rights, particularly if the scope of protection afforded by our intellectual property rights is limited by the laws and regulations of certain jurisdictions or pursuant to court judgments or other legal proceedings;
- we might not have been the first to file patent applications covering certain of our inventions;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- we may not develop additional proprietary technologies that are patentable;
- 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
- our patents may be rendered invalid or unenforceable as a result of legal challenges by our competitors; and
- our competitors might conduct research and development activities in countries where we do not have patent rights and use the information learned to develop competitive drugs for sale in our major markets.

*Failure to protect our know-how, trade secrets and other confidential proprietary information may adversely affect our competitiveness.*

In addition to patents and pending patent applications, we rely on know-how, trade secrets and other confidential proprietary information that cannot be patented to maintain our competitive position. To protect such intellectual property, we generally enter into non-disclosure and confidentiality agreements with employees, business partners, consultants, advisors and other third parties. Our standard employment contract contains a confidentiality clause and an assignment clause, under which we own all the rights to all inventions, technologies, know-how and trade secrets derived during the course of our employee’s work.



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We also enter into standard non-compete agreements with our key personnel. Additionally, we require our collaborating research institutions or other individuals to sign contracts with provisions that limit their ability to disclose certain data and other information obtained during the course of their research. However, we cannot assure you that our employees or other third parties will not intentionally or inadvertently make unauthorized disclosures or uses of our know-how, trade secrets and other confidential proprietary information. We also cannot guarantee the physical and cyber security of our information technology systems from data breaches and malicious attacks. Despite measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully gain access to, obtain or use information that we regard as proprietary without our consent. Moreover, there may not be adequate remedies readily available to mitigate their unauthorized use or disclosure of our confidential proprietary information. We may hence be unable to sufficiently protect our trade secrets and proprietary information and other parties may attempt to or successfully make use of our know-how, trade secrets and other confidential proprietary information to produce drugs that erode our competitive position. Any enforcement and/or remedial measures that we take may be expensive and time-consuming, and the eventual outcomes may be unfavorable.

In addition, while we typically require our employees who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, 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. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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

Many of our employees, consultants and advisors, including our senior management, were previously employed at other pharmaceutical or biotech companies, including our competitors or potential competitors. Some of these employees, consultants and advisers executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees 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 that third parties have an interest in our patents as an inventor or co-inventor. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but such claims may rise in the future. If we fail in defending any such claims,

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in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Failure to adequately protect our trade names, trademarks and other intellectual property may affect our ability to build brand recognition.***

We conduct our business under the brand name of “Qyuns (荃信).” As of the Latest Practicable Date, we had registered 83 trademarks in the PRC and Hong Kong. As of the same date, we were the registered owner of 21 domain names in the PRC. However, our measures to protect intellectual property rights afford limited protection and policing unauthorized use of our intellectual property may be difficult and expensive. In addition, the enforceability, scope and validity of laws governing intellectual property rights in China are uncertain and still evolving. We cannot guarantee that we will be able to detect unauthorized use of our intellectual property rights or take appropriate steps to enforce them in a timely and effective manner. Moreover, attempts to protect our intellectual property rights through litigation could result in substantial costs and divert resources and management attention.

Furthermore, our registered and unregistered trade names or trademarks may be challenged, infringed, circumvented or declared generic or infringing on other marks. We may not be able to protect our rights to these trade names and trademarks, which we need to build brand recognition among potential partners or customers in our markets of interest. 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, our business could be materially adversely affected.

Additionally, there is no guarantee that we will always be able to successfully register our trade names and trademarks. Failure to do so may prevent us from using our trade names and trademarks under the protection of the relevant laws and regulations, and we risk being accused of infringing other intellectual property rights. In addition, at times, competitors may adopt trade names or trademarks similar to our own and impede our ability to build brand recognition. Over the long term, failure to establish brand recognition based on our trade names and trademarks may prevent us from competing effectively and diminish our future prospects.

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### RISKS RELATING TO OUR OPERATIONS

***We may fail to successfully manage our growth and expand our operations.***

Since our inception, we have sought to expand our business through organic growth. As we advance our drug candidates through clinical trials and prepare for potential commercial launch for multiple drug candidates in the future, we will need to expand our development and manufacturing capabilities and seek cooperation opportunities for the sales and marketing of our future approved drugs.

Our recent growth and any future growth will impose significant added responsibilities on members of management, including (i) identifying, recruiting and integrating additional employees in accordance with our development plan; (ii) managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and (iii) improving our operational, financial and management controls, reporting systems and procedures. We would also need to secure and manage additional collaborative relationships with various strategic partners, such as Zhongmei Huadong, suppliers, CROs and other third parties.

However, we cannot guarantee that we will be able to successfully execute our development strategies. To a certain extent, our future growth may be affected by changes in regulatory, economic or political conditions beyond our control, such as changes in China’s general economic conditions, the biotech industry and relevant government regulations.

It is difficult to predict our future growth based on our historical and operating data. We also cannot assure you that our future development plan will materialize. Investors should not rely solely on our historical results of operations to predict our future performance. Additionally, our expansion plans are based on our forward-looking assessment of market prospects. We cannot assure you that our assessments will prove correct.

***We may be unable to attract and retain senior management and qualified clinical or research and development personnel.***

Our operation depends in part on our continued ability to attract, retain and motivate senior management and qualified management, clinical and scientific personnel. We believe their efforts, connections and industry expertise are key to our business development.

The loss of services of any of our key management personnel may impede the achievement of our research, development and commercialization objectives. We cannot guarantee that we will be able to promptly hire and integrate qualified replacements. Replacing executive officers or senior management personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize biologic drugs like those we develop. Competition to hire from this limited pool

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is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotech companies for similar personnel.

In addition, the future growth of our business will depend partly on our ability to attract and retain qualified personnel on reasonable terms, particularly those involved in our clinical and research and development operations. We may need to compete with other drug companies for employees with the relevant qualifications and experience. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisers may be employed by others entities and may have commitments under consulting or advisory contracts with employers that may limit their availability to us. Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited. Any inability to hire and retain personnel with the talent and technical skill that we need to conduct our business could materially adversely affect our business, financial condition, results of operations and prospects.

***We have entered into collaborations agreements, and may form or seek other collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We have entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. See “Business—Collaboration with Zhongmei Huadong” for further details. We may continue to explore a variety of possible strategic collaborations or license opportunities in an effort to gain access to additional drug candidates, technologies or commercialization resources.

We face significant competition in seeking appropriate strategic partners and the negotiation process, which 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 a majority of them may be deemed to be at too early of a stage of development for collaborative effort and potential partners may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability.

In addition, collaborations involving our drug candidates are subject to various risks, including, but not limited to:

- collaboration partners have significant discretion in determining the development or commercialization strategy for our drug candidate during collaboration, which may be different from what we expected and may be ineffective;

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- the development or commercialization capabilities of our partners may not be as strong as we expected;
- collaboration partners may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaboration partners may not commit sufficient resources to the development or sales and marketing of one or more of our drug candidates;
- we could grant exclusive rights to our collaboration partners that would prevent us from collaborating with others;
- collaboration partners 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;
- collaboration partners may not aggressively or adequately pursue litigation against generic filers or may settle such litigation on unfavorable terms, as they may have different economic interests than ours, and such decisions could negatively impact any royalties we may receive under our license agreements;
- we may encounter material disputes with collaboration partners regarding the terms of our collaboration, which could lead to disruption of the development or commercialization of our drug candidates and litigations that could be time-consuming and expensive; and
- collaborations may be terminated and, if terminated, may result in a need for additional time and capital to pursue alternative partners for the development or commercialization of the applicable drug candidates;

Therefore, we may not be able to realize the benefit of current or future collaborations, if we are unable to successfully integrate such collaborations with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other financial benefits that justify such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail or delay the development or commercialization of one or more of our drug candidates, reduce the scope of any sales or marketing activities, or increase our expenditures

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and undertake such development or commercialization activities at our own expense. As a result, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

***Our employees, CROs, collaboration partners and others with whom we deal may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could harm our reputation and subject us to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.***

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, CROs, collaboration partners and others with whom we deal. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: (i) comply with the laws of the NMPA and other regulatory authorities; (ii) provide true, complete and accurate information to the NMPA and other regulatory authorities; (iii) comply with healthcare fraud and abuse laws in China; or (iv) report financial information or data accurately or to disclose unauthorized activities to us. If we obtain NMPA approval for any of our drug candidates and begin commercializing those drugs in China, our potential exposure under relevant laws will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators of our clinical trials and our use of information obtained in the course of patient recruitment for clinical trials.

It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***We may be required to pay late payment fines or other penalties in connection with our failure to contribute to social insurance and housing provident funds.***

In accordance with applicable PRC laws and regulations, we are obliged to contribute to social insurance and housing provident funds for our employees. During the Track Record Period, we did not fully contribute to social insurance and housing provident funds for some of our employees and engaged third-party agents to make the payment of social insurance and housing provident fund on behalf of us for certain employees. We made full provisions for the total amount of such shortfall of RMB3.8 million, RMB5.4 million and RMB3.9 million to our consolidated statement of profit or loss and other comprehensive income for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. Our PRC Legal Advisors have advised us that, under the Regulations on Administration of Housing Provident Fund (《住房公積金管理條例》), if we fail to pay housing provident fund

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contributions within the prescribed deadlines, we may be subject to an order by the relevant people's court to make such payments. According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), for outstanding social insurance fund contributions that we did not fully pay within the prescribed deadlines, the relevant PRC authorities may demand that we pay the outstanding social insurance contributions within a stipulated deadline and we may be liable for a late payment fee equal to 0.05% of the outstanding contribution amount for each day of delay. If we fail to repay the outstanding social insurance contributions within the stipulated period, we may be liable to a fine of one to three times the outstanding contribution amount. As of September 30, 2023, the outstanding balance of our shortfall in contribution amounted to RMB4.5 million for social insurance and RMB8.2 million for housing provident fund. Therefore, as advised by our PRC Legal Advisors, we could be subject to fines of up to RMB13.5 million in relation to the shortfall in our contribution to social insurance and a late fee of 0.05% of the outstanding amount for each day of delay. As advised by our PRC Legal Advisors, the risk of us being penalized for such shortfall is remote, provided that we rectify such shortfall in a timely manner after receiving notices from the relevant PRC authorities. As of the Latest Practicable Date, we had not received any order of correction from the competent authority, or any complaint or labor arbitration application from any of our employees, as a result of any such arrangement. However, we cannot assure you that the competent authority will not require us to rectify any non-compliance or to pay any penalty related thereto.

***We may be required to pay administrative fines for our failure to register some of our lease agreements with housing administration authorities.***

As of the Latest Practicable Date, we had not completed the administrative filings of the lease agreements relating to seven properties we leased for business purposes, with an aggregate GFA of 1,229 sq.m. As registration of the lease agreement will require the cooperation of the landlord, we cannot assure you that we can complete the registration of such lease agreement in a timely manner or at all. According to applicable PRC administrative regulations, the lessor and the lessee of a lease agreement are required to file the lease agreement with relevant governmental authorities within 30 days after the execution of the lease agreement. If the filing is not made, the governmental authorities may require that the filing be made within a stated period of time, failing which they may impose a fine ranging from RMB1,000 to RMB10,000 for each agreement that has not been properly filed. It is not clear under applicable PRC laws if the fine will be borne by the lessor or lessee. According to applicable PRC administrative regulations, lessors of the related leases need to provide us with certain documents (such as their business licenses or identification information) in order to complete the administrative filing. There can be no assurance that the lessors of our leased properties will be cooperative in the process of completing the filings. If we fail to complete the administrative filings within the period required by the relevant governmental authorities and the relevant authorities determine that we shall be liable for failing to complete the administrative filings of all the relevant lease agreements, we may be subject to a fine of up to RMB10,000 for each such lease agreement or such other fine which may be determined by relevant government authorities.

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***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, manufacturing facilities and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste products. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain statutory employees’ social insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

***Changes in social trends and political policies related to environmental, social, and governance issues may adversely affect our business operation.***

As a biotech company, we are subject to potential risks arising from changes in social trends and political policies related to environmental, social, and governance (ESG) issues, such as public perception with respect to animal testing for the R&D of biologic drugs. Changes in social trends and political policies related to ESG issues could impact our business model in several ways. For example, if there is a shift towards more stringent regulations on environmental protection or animal welfare, we may face increased compliance costs and operational challenges. Similarly, if there is a growing demand for biologic drugs that are developed and manufactured using environmentally friendly process, we may need to adapt our pipeline and invest in new technologies and process to reduce our environmental footprint. Moreover, changes in political policies related to ESG issues may impact our access to funding and other resources that are critical to our growth and success. For instance, if there is a change in government policies that restricts funding for biotech companies that do not meet certain ESG criteria, we may face challenges in securing financing for our business activities.



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*Should we fail to detect or prevent violations of applicable anti-bribery laws by our employees, researchers, marketing and sales personnel and other business partners, we may experience material adverse effects on our business and be subject to significant penalties.*

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials to obtain or retain business or secure any other improper advantages. Within the healthcare industry, violations of anti-bribery and anti-corruption laws may include improper payments that facilitate outcomes in research studies and/or drug supply negotiations or opportunities to sell drugs or other healthcare products at hospitals and other medical institutions. Although we have put in place policies and procedures that ensure that we and our employees comply with anti-bribery laws, we cannot guarantee that our research and development staff, sales and marketing personnel and other employees, as well as third parties that we collaborate with such as CROs, hospitals and medical professionals will fully comply with anti-bribery and anti-corruption regulations at all times. We also cannot assure you that we will be able to detect and prevent all instances of improper practices with respect to our clinical trials and other aspects of our business. In the event that our employees or other third party collaborators such as our research and development staff, sales and marketing personnel and other employees do not adhere to anti-bribery and anti-corruption laws, we may be subject to investigations, sanctions or fines that generate negative publicity and substantially harm our reputation, business and prospects.

*Negative publicity about us, our Shareholders and affiliates, our brand and management may materially and adversely affect our business, reputation and trading price of our H Shares.*

We believe that market awareness and recognition of our brand image is important to our commercial prospect. Despite our efforts to promote our brand image, we may not be successful in doing so. Over the long term, negative publicity may materially and adversely affect our business and brand so as to reduce the trading price of our H Shares and diminish our competitive position.

As we continue to grow our business, we may find it necessary to expand our network of collaborators to enhance our marketing and branding efforts. Since we have limited control over such parties, we cannot guarantee that our efforts will be successful, nor that they will perform according to the standards expected. Any actions on their part that reflect negatively on our business or generate negative publicity for us may impede our efforts to establish our industry reputation.

Furthermore, negative publicity about us, our Shareholders and affiliates, alleged misconduct or improper activities or negative rumors relating to us, our management, employees, business partners or affiliates may arise from time to time in the internet and other media sources. They may harm our business and results of operations even if they are unsubstantiated. There is no guarantee that our efforts to defend ourselves against such negative publicity or rumors, or to address them internally, will be successful. Any regulatory inquiries or investigations against our directors and senior management, business partners or

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other affiliates regarding any perceived unethical, fraudulent or other inappropriate conduct may be particularly harmful to our reputation regardless of the merits or final outcome. In turn, this may affect our ability to grow our business and attract customers, suppliers and talented employees.

We are also particularly susceptible to negative media about the drug industry in general or particular drugs or services. Such negative media may result from the actions of competitors or other industry players, over whom we have no control. It is possible that the PRC government may promulgate laws and regulations that seek to address the source and reasons for such negative media. We cannot guarantee that we will be able to adapt to such laws and regulations in a timely and effective manner, including adequate management of the related compliance costs.

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

From time to time, we may be directly or indirectly involved in legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. In particular, we face an inherent risk of product liability as a result of the clinical testing and any future commercialization of our drug candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaboration partners for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or the eventual outcome of such product liability claims, we may be subject to the following consequences:

- less interest in our drug candidates and reduced demand for our drugs;
- reputational damage;
- withdrawal of clinical trial participants;
- inability to commercialize drug candidates;
- loss of revenue;
- costs incurred to defend legal proceedings;
- substantial monetary damages payable to trial subjects or customers; and
- product recalls, withdrawals or the imposition of labeling, marketing or promotional restrictions that limit our ability to commercialize our drug candidates.

## RISK FACTORS

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If we are unable to defend ourselves against such claims, we may be subject to, among other things, civil liability for adverse events or other losses caused by our products and to criminal liability and the potential revocation of our business licenses if our products are found to be defective.

In addition to product liability claims, our employees may also sue us for labor-related disputes or occupational injuries, and we are subject to risks associated with having limited control over the behavior of employees or other business partners who may intentionally or unintentionally harm the interests of our customers. Any claims, disputes and legal proceedings brought against us could result in substantial costs and divert capital resources and management attention, even if we should mount a successful defense. We may suffer damage to our reputation regardless of the merits or outcome, leading to material adverse effects on our business, financial position and brand value.

Existing PRC laws and administrative regulations require us to maintain liability insurance to cover product liability claims on clinical trials. Any product liability insurance for clinical trials, when obtained, may be prohibitively expensive, or may not fully cover our potential liabilities. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drug candidates we develop. Moreover, claims that may be brought against us could result in a court judgment or settlement for such amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

***We are exposed to risks in connection with failing to detect and prevent fraud, negligence or other misconduct committed by third parties.***

Our information management system and internal control procedures are designed to monitor our operations and overall compliance. However, we cannot guarantee that they will always enable us to detect, prevent and take remedial measures in relation to fraud, negligence or other misconduct (accidental or otherwise) committed by our employees, business partners, suppliers, customers or other third parties in a timely and effective manner. There will therefore continue to be risks that fraud, negligence and other misconduct (accidental or otherwise) may occur and cause negative publicity, which may have an adverse effect on our brand and reputation. Although we have limited control over the behavior of any of these parties, we may be viewed as at least partially responsible for their conduct. We may become, or be joined as, a defendant in litigation or other administrative or investigative proceedings and be held accountable for injuries or damages sustained by our employees, business partners, suppliers,

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## RISK FACTORS

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customers or other third parties from time to time. To the extent that we cannot recover related costs from the employees, business partners, suppliers, customers or other third parties involved, we may experience material adverse effects on our business, financial position and results of operations.

*We may experience additional challenges related to the COVID-19 pandemic.*

The outbreak of COVID-19, a highly contagious disease known to cause respiratory illness, had caused an adverse impact on the economy and social conditions in China and other affected countries since late 2019, and had an impact on our industry and caused temporary suspension of some of our clinical trials. Many countries imposed unprecedented measures to halt the spread of the COVID-19 pandemic, including city lockdowns and travel restrictions. The Chinese government had implemented emergency measures in various key cities or regions across the country, including Taizhou, in response to the outbreak of the Delta variant since July 2021 and the Omicron variant since November 2021, including travel restrictions, mandatory cessations of business operations, mandatory quarantines, and limitations on social and public gatherings. These measures affected our research and development and manufacturing activities. In particular, we experienced varying extents of delay in our clinical trials in 2022 when the research institution we engaged were under lockdown. For example, our Phase II clinical trial of QX002N for AS, which commenced in January 2022, experienced delay in patient enrollment for approximately two months and interruption in follow-up visits of some patients due to COVID-19-related lockdown measures in cities where our clinical trial sites/patients were located. In the Phase Ib clinical trial of QX005N for AD, due to COVID-19-related lockdown measures, one patient was lost to follow-up, whose data were considered invalid.

Since December 2022, the Chinese government has taken measures to lift the pandemic-related restrictions on social and economic activities to facilitate people’s return to normalcy. However, there is still uncertainty as to the future development of the COVID-19 pandemic. There could be a resurgence of the disease and infections could increase again across the country. The continuation or any future recurrence of COVID-19 may adversely affect our business operations, such as causing temporary delay of our existing and future clinical trials and reducing working capacity of our employees. Such occurrences may have the effect of increasing our drug development costs and affect our ability to conduct our business operations.

Although we constantly monitor the status of the COVID-19 pandemic, it is affected by factors beyond our control. We cannot guarantee that any mitigation measures we may take will be sufficient against the effects of a global pandemic. In the event that we are unable to minimize the negative effects of any future recurrence of COVID-19 on our business, we may experience material adverse effects on our financial statements and results of operations.

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*Our insurance coverage may not sufficiently cover the risks related to our business operations.*

We maintain insurance policies that we believe are customary with standard commercial practice in the drug industry and as required under the relevant PRC laws and regulations. However, we cannot guarantee you that our insurance policies will provide adequate coverage for all the risks in connection with our business operations. For example, although we maintain liability insurance covering our clinical trials as required under PRC laws and regulations, our coverage may be insufficient to cover any amounts payable under court judgments or settlements. Should we incur substantial amounts in product liability claims, and be unable to cover these with our existing insurance policies or internal resources, we may be forced to suspend other key operations, such as the conduct of clinical trials, to divert funds from other aspects of our business.

Moreover, there are certain losses for which insurance is not available in China on commercially practicable terms, such as losses suffered due to business interruptions, earthquakes, typhoons, flooding, war or civil disorder. We may be required to bear our losses to the extent that they are not covered by insurance, or that our insurance coverage is insufficient, and such amounts could be substantial. We could suffer significant costs and diversion of our resources as a result.

*Our information technology systems, or those of our CROs or other service providers or consultants, may fail or suffer security breaches.*

Despite the implementation of security measures, our internal computer systems and those of our CROs, service providers or consultants are vulnerable to damage or interruption caused by, among others, power outages, computer viruses, phishing attacks, ransomware, worms, unauthorized access, telecommunication failures, cyber-attacks, natural disasters, terrorism and war. Should such events occur and interrupt our operations, we may experience a material disruption to our business operations.

In our ordinary course of business, we collect and store sensitive information, including the personal information of our employees, various intellectual property (including trade secrets), research and development information, sales and marketing strategies and key business and financial data. We manage and maintain our information and data through on-site systems and third-party vendors. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our sites or third-party vendors may materially and adversely affect our business operations by damaging key data and equipment. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. There is no guarantee that our disaster recovery and automatic

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## RISK FACTORS

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recovery systems will be able to retain and recover all the equipment or data affected by shutdowns or service disruptions. In addition, we may not have adequate insurance coverage to compensate for losses associated with such events.

Furthermore, we are vulnerable to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of sensitive information maintained in our information systems and those of our vendors, including confidential data on our employees, customers, suppliers and clinical trial subjects. Outside parties may attempt to penetrate our information systems or those of our vendors, or fraudulently induce our employees or our vendors’ employees to disclose sensitive information through means such as viruses, phishing and cyber-attacks. The number and complexity of these threats continue to increase over time. In the event of a material breach of our information technology systems or those of our vendors, our business partners, customers or other industry players may have a negative perception of the effectiveness of our security measures, and we may experience harm to our reputation and credibility. We may also be compelled to expend substantial financial resources to repair or replace our information systems. In addition, we may be subjected to collective actions and/or claims from individuals respecting issues related to data privacy laws and regulations, such as misuse or inappropriate disclosure of data and unfair or deceptive practices.

We cannot guarantee that our internal control procedures will always be sufficient to identify and mitigate threats to our information systems. The development and maintenance of our information systems is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. We may not always be able to adapt our internal control procedures and update our information systems in a sufficiently timely or effective manner to eliminate all such risks. Additionally, the more we outsource protection and upgrading of our information systems to vendors, engage in electronic transactions and rely on cloud-based information systems, the less control we have over the risks to our information systems. To the extent that disruptions or security breaches of our information systems or those of our vendors, CROs, service providers or other consultants compel us to temporarily suspend our business operations, we may experience delays to the development and commercialization of our drug candidates.

***Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity.***

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information in China is rapidly evolving and is likely to remain uncertain for the foreseeable future. There are numerous laws that protect the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. Regulatory authorities may continue to introduce additional legislative and regulatory proposals concerning personal data protection.

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Measures for the Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment) (《個人信息出境安全評估辦法(徵求意見稿)》) was published by the Cyberspace Administration of China in 2019, which may, upon enactment in current form, require security assessment before transferring personal information collected in China abroad. Moreover, the Standing Committee of the NPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), which became effective on November 1, 2021, sets forth detailed rules on handling personal information and legal responsibilities and also strengthen the punishment for illegal process of personal information. Under the Personal Information Protection Law of the PRC, healthcare relevant personal information, including the information collected during clinical trials, shall be deemed as “sensitive personal information” and shall be under strict protection. Furthermore, GCP requires that the privacy of trial subjects and the confidentiality of the relevant information shall be protected.

Moreover, the Data Security Law of the PRC (《中華人民共和國數據安全法》) which has taken effect on September 1, 2021, provides that relevant authorities will establish the measures for the cross-border transfer of import data, if any company violates the Data Security Law of the PRC to provide important data outside China, such company may be punished by administration sanctions, including penalties, fines, and/or may suspension of relevant business or revocation of the business license. The Cyberspace Administration of China published Measures for the Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment) (《個人信息出境安全評估辦法(徵求意見稿)》) in 2019, which may, upon enactment in current form, require security assessment before transferring personal information collected in China abroad. Moreover, the Outbound Data Transfer Security Assessment Measures (the “Outbound Data Transfer Security Assessment Measures”) (《數據出境安全評估辦法》) was published on July 7, 2022 and became effective on September 1, 2022, which specifies that data processors who intend to provide important data and personal information that are collected and generated in the operation within the territory of the PRC to overseas shall be subject to security assessment. The Outbound Data Transfer Security Assessment Measures further stipulate the process and requirements for the security assessment. However, it remains uncertain how the PRC government authorities will regulate companies under such circumstances if the Outbound Data Transfer Security Assessment Measures are fully implemented as-is. These bring more uncertainties with respect to the application and enforcement of the newly published measures, and we may be subject to such outbound data security assessment. We will closely monitor and assess any relevant legislative and regulatory development and prepare for a security assessment when necessary.

Compliance with these and any other applicable laws, regulations, standards and obligations relating to data privacy, security and transfers is a rigorous and time-intensive process and may cause us to incur additional operational costs or require us to modify our data processing practices and processes. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face proceedings against us by data protection authorities and governmental entities, which could subject us to significant fines, penalties, judgments, negative publicity and reputational damage, and may otherwise materially and adversely affect our business, financial condition and results of operations.

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*We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control.*

Natural disasters, acts of war, terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors 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 conditions and results of operations.

### **RISKS RELATING TO THE [REDACTED]**

*There has been no prior public market for our H Shares and an active [REDACTED] market for our H Shares may not develop.*

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

*The [REDACTED] and [REDACTED] of our H Shares may be volatile, which could result in substantial losses for investors who [REDACTED] our H Shares in the [REDACTED].*

The [REDACTED] and [REDACTED] of our H Shares may be highly volatile. Several factors beyond our control such as variations in our revenue, earnings and cash flow, strategic alliances, the addition or departure of key personnel, litigation, the removal of the restrictions on H share transactions or volatility in [REDACTED] and changes in demand for our products may cause significant and sudden changes to the [REDACTED] and [REDACTED] of our H Shares. Furthermore, the [REDACTED] of our H Shares could also decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the public market, or the issuance of new shares or other securities, or the perception that such sales or issuances may occur. New shares or share-linked securities issued by our Company may also confer rights and privileges that take priority over those conferred by the H Shares.



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The Stock Exchange and other securities markets have, from time to time, experienced significant price and trading volume volatility that are not related to the operating performance of any particular company. This volatility may also materially and adversely affect the [REDACTED] of our H Shares.

*Since there will be a gap between the [REDACTED] and [REDACTED] of our H Shares, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares may fall during the period before [REDACTED] of our H Shares begin.*

The [REDACTED] of our H Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the H Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be on a later date than the [REDACTED]. As a result, investors may not be able to sell or otherwise [REDACTED] the H Shares during that period. Accordingly, Shareholders are subject to the risk that the [REDACTED] of the H Shares could be lower than the [REDACTED] when [REDACTED] begins as a result of adverse market conditions or adverse developments that may occur between the time of [REDACTED] and the time of initial [REDACTED].

*Potential investors will experience immediate and substantial dilution as a result of the [REDACTED].*

Potential investors will pay a price per H Share in the [REDACTED] that substantially exceeds the per H Share value of our tangible assets after subtracting our total liabilities as of September 30, 2023. Therefore, purchasers of our H Shares in the [REDACTED] will experience a substantial immediate dilution in *pro forma* net tangible assets, and our existing Shareholders will receive an increase in the *pro forma* adjusted net tangible assets per Share on their Shares. As a result, if we were to distribute our net tangible assets to the Shareholders immediately following the [REDACTED], potential investors would receive less than the amount they paid for their H Shares. For more information, see “Appendix II—Unaudited Pro Forma Financial Information” to this document.

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

All of our [REDACTED] Shares may be converted into H Shares and such converted Shares may be [REDACTED] or [REDACTED] on an overseas stock exchange. Any [REDACTED] or [REDACTED] of the converted Shares on an overseas stock exchange shall also comply with the regulatory procedures, rules and requirements of such stock exchange. However, the PRC Company Law provides that in relation to the [REDACTED] of a company, the shares of that company which are issued prior to the [REDACTED] shall not be transferred within one year from the date of the [REDACTED]. Therefore, upon the completion of the relevant filing procedure, shares currently held on our [REDACTED] Share register may be [REDACTED], after the conversion, in the form of H Shares on the Stock Exchange after one year of the [REDACTED], which could further increase the supply of our H Shares in the market and could negatively impact the [REDACTED] of our H Shares.

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## RISK FACTORS

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*We cannot guarantee the accuracy of facts, forecasts and other statistics obtained from official government sources or other sources contained in this document.*

Certain facts, statistics and data contained in this document relating to the pharmaceutical industry in and outside China have been derived from various official government publications, industry associations, independent research institutions, third party reports and/or other publicly available sources we generally believe to be reliable, as well as a report prepared by Frost & Sullivan that we commissioned. We believe that the sources of such information are appropriate sources for such information, but the information has not been independently verified by us or any other party involved in the [REDACTED] and no representation is given as to its accuracy.

*There is no assurance whether and when we will pay dividends, which is subject to restrictions under PRC law.*

No dividend had been paid or declared by our Company during the Track Record Period. Under the applicable PRC laws, the payment of dividends may be subject to certain limitations. The calculation of our profit under applicable accounting standards differs in certain respects from the calculation under IFRS. As a result, we may not be able to pay a dividend in a given year even if we were profitable as determined under IFRS. Our Board may declare dividends in the future after taking into account our results of operations, financial condition, cash requirements and availability and other factors as it may deem relevant at such time. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the PRC laws and regulations and requires approval at our shareholders' meeting. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution.

*Dividends payable to investors and gains on the [REDACTED] of our H Shares may be subject to PRC income taxes.*

Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to different tax obligations with respect to dividends received from us or gains realized upon the [REDACTED] or other disposition of our H Shares. Non-PRC individuals are generally subject to PRC individual income tax under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) with respect to PRC source income or gains at a rate of 20% unless specifically exempted by the tax authority of the State Council or reduced or eliminated by an applicable tax treaty. We are required to withhold related tax from dividend payments. Pursuant to applicable regulations, domestic non-foreign-invested enterprises issuing shares in Hong Kong may generally, when distributing dividends, withhold individual income tax at the rate of 10%. However, withholding tax on distributions paid by us to non-PRC individuals may be imposed at other rates pursuant to applicable tax treaties (and up to 20% if no tax treaty is applicable) if the identity of the individual holder of H shares and the tax rate applicable thereto are known to us. There is uncertainty as to whether gains realized upon disposition of H shares by non-PRC individuals are subject to PRC individual income tax.

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Non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not related to such establishments or premises are subject to PRC EIT at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, which may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the non-resident enterprise resides.

Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including HKSCC Nominees). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities’ verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by non-resident enterprise holders of H shares through the sale or transfer by other means of H shares.

There remains significant uncertainty as to the interpretation and application of the relevant PRC tax laws by the PRC tax authorities, including whether and how individual income tax or EIT on gains derived by holders of our H Shares from their disposition of our H Shares may be collected. If any such tax is collected, the value of our H Shares may be materially and adversely affected.

***Fluctuations in Renminbi exchange rates may lead to foreign exchange losses and materially and adversely affect our ability to pay dividends to holders of our H Shares.***

We expect that a substantial majority of our revenue will be denominated in Renminbi. A portion of our revenues may be converted into other currencies in order to meet our foreign currency obligations. For example, we need to obtain foreign currency to make payments of declared dividends, if any, on our H Shares. Shortages in availability of foreign currency may then restrict our ability to remit sufficient foreign currency to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations.

The [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our H Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

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

This document contains certain forward-looking statements and information relating to us that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words “aim,” “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “going forward,” “intend,” “ought to,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and similar expressions, as they relate to us or our business, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, business operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. Should one or more of these risks or uncertainties materialize, or if any of the underlying assumptions prove incorrect, actual results may diverge significantly from the forward-looking statements in this document. Whether actual results will conform to our expectations and predictions is subject to a number of risks and uncertainties, many of which are beyond our control, and reflect future business decisions that are subject to change. In light of these and other uncertainties, the inclusion of forward-looking statements in this document should not be regarded as representations that our plans or objectives will be achieved, and investors should not place undue reliance on such forward-looking statements. All forward-looking statements contained in this document are qualified by reference to the cautionary statements set out in this section. Subject to the ongoing disclosure obligations of the Listing Rules or other requirements of the Stock Exchange, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise.

*You should read this entire document carefully and should not consider or rely on any particular statements in published media reports without carefully considering the risks and other information contained in this document.*

Prior to the publication of this document, and subsequent to the date of this document but prior to the completion of the [REDACTED], there may have been or may be press and media coverage regarding us, our business, our industry and the [REDACTED]. Such press and media coverage may include references to information that do not appear in this document or is inaccurate. We have not authorized the publication of any such information contained in such press and media coverage. Therefore, we make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the press or media and do not accept any responsibility for the accuracy or completeness of any financial information or forward-looking statements contained therein. To the extent that any of such information is inconsistent or conflicts with the contents of this document, we expressly disclaim responsibility for them. Accordingly, prospective investors should only rely on information included in this document and not on any of the information in press articles or other media coverage in deciding whether or not to invest in our [REDACTED]. By applying to purchase our H Shares in the [REDACTED], you will be deemed to have agreed that you have not and will not rely on any information other than that contained in this document, the [REDACTED], and any formal announcements made by us in Hong Kong in relation to our [REDACTED].