

RISK FACTORS

An [REDACTED] in our Shares involves various risks. You should carefully read and consider all of the information in this document including the risks and uncertainties described below before deciding to make any [REDACTED] in our Shares.

The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] of our Shares could decline and you may lose all or part of your [REDACTED]. You should seek professional advice from your relevant advisers regarding your prospective [REDACTED] in the context of your particular circumstances.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

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

Our revenue and profitability are substantially dependent on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully commercialize our drug candidates. The success of our drug candidates will depend on a number of factors, including: (i) generating favorable safety and efficacy data from preclinical studies and clinical trials, successful patient enrollment and completion of trials, and maintaining an acceptable safety profile after approval; (ii) securing sufficient resources and clinical supplies, as well as the performance, compliance, and capabilities of our CROs and collaborators; (iii) obtaining regulatory approvals, managing protocol modifications, and ensuring commercial manufacturing capacity; (iv) successfully launching commercial sales and obtaining favorable reimbursement from third-party payers; and (v) effectively competing in the market while obtaining, maintaining, enforcing, and defending our intellectual property rights.

As of the Latest Practicable Date, all of our other drug candidates were in various phases of preclinical and clinical development. If we encounter any challenges arising from one or more of the aforementioned factors, we could experience significant delays or difficulties in obtaining approvals for and commercializing our drug candidates.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of preclinical studies and early phases of clinical trials may not be predictive of future trial results.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. As of the Latest Practicable Date, four of our drug candidates, namely ES102, ES014, ES104 and ES009, were in clinical development. For details of our pipeline and clinical development of our product candidates, see “Business — Our Pipeline.”

While we believe our drug candidates have the potential to be innovative and differentiated globally, we cannot guarantee that we will be able to realize such potential for any of our drug candidates. Failure can occur at any time during the drug development process, which would result in a material and adverse effect on our business, financial condition and results of operations including: (i) delays or denials by regulators, ethics committees, or other review bodies to initiate or conduct clinical trials; (ii) suspension or termination of trials due to negative results, safety concerns, or adverse events; (iii) difficulties negotiating acceptable terms with CROs, hospitals, or contract manufacturers; (iv) manufacturing and quality control issues or insufficient clinical supply; and (v) slower-than-expected patient enrollment or higher subject dropout rates.

RISK FACTORS

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors. In the case of any trials we conduct, results may also differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. We cannot guarantee that the results from our future research and development efforts will be favorable based on currently available clinical and preclinical data, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates.

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

The biopharmaceutical industry in which we operate is intensely competitive and subject to rapid and significant technological changes. While we focus on developing drug candidates with the potential to become novel or highly differentiated drugs, we continue to face competition with respect to our current drug candidates, and any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major multinational pharmaceutical companies and biopharmaceutical companies worldwide. We are developing our drug candidates for the treatment of cancer in markets where there are companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of indications which our drug candidates also target. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on different approaches. For details, see "Business — Our Pipeline." Potential competitors also include academic institutions, governmental authorities and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for, development, manufacturing and commercialization of drug.

Many of our competitors have substantially greater financial, technical, and other resources than we do, such as larger research and development staff and experienced marketing and manufacturing infrastructure. Mergers and acquisitions in the biopharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval from the NMPA, the FDA or other comparable regulatory authorities more rapidly than we are able to and may be more effective in selling and marketing their products. Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any drug candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do.

We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success.

Although our effort will primarily focus on the continued clinical testing, potential approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to identify, license, discover, develop, or commercialize additional drug candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial

RISK FACTORS

potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for selected indications may not yield any commercially viable products. If we misjudge a drug candidate’s potential, we may relinquish valuable rights or misallocate resources, adversely affecting our growth.

Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization due to: (i) unsuccessful research or business development methodologies or search criteria; (ii) identification of harmful side effects or other characteristics that make drug candidates unmarketable or unlikely to receive approval; and (iii) insufficient human and financial resources to identify additional therapeutic opportunities or develop suitable candidates, limiting our ability to diversify our portfolio. We have strategically in-licensed two clinical-stage drug candidates from Inhibrx and Compass, respectively, and entered into a strategic partnership with Astellas to collaborate on the novel bispecific macrophage engager programs derived from our BiME[®] platform. However, there can be no assurance that such license and collaboration will deliver the expected results.

If we encounter delays or difficulties enrolling subjects in our clinical trials, our clinical development progress could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials or may experience delays in the development progress for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the NMPA, the FDA, or similar regulatory authorities, or if there are delays in the enrollment of eligible subjects as a result of the competitive clinical enrollment environment. For example, we experienced temporary enrollment challenges in ES102’s phase 2 trial with toripalimab for patients with advanced NSCLC in China, primarily due to a higher-than-expected volume of competing clinical trials conducted in 2024, which resulted in the initial phase of the trial advancing at a slower pace than projected.

Subject enrollment for our clinical trials may be affected by other factors, including (i) the severity of the disease under investigation; (ii) the size and nature of the patient population; (iii) the design and eligibility criteria of the trial; (iv) perceived risks and benefits of the drug candidate; (v) our resources to facilitate timely enrollment; (vi) physician referral practices; (vii) availability of competing therapies in trials; (viii) efforts of investigators or trial sites to screen and recruit patients; and (ix) proximity and availability of clinical trial sites. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Our drug candidates may cause undesirable AEs or have other properties that could delay or prevent their regulatory approval, and limit the commercial profile of an approved label, thus diminishing the commercial viability of our drug candidates.

Undesirable AEs caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive label, a delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. Trial results could reveal unacceptable severity or prevalence of AEs, leading to trial termination or regulatory denial of approval. AEs could also affect recruitment, trial completion, and result in liability claims, significantly harming our reputation, business, and financial condition.

Additionally, if we, our licensing partners, or others identify undesirable side effects caused by our drug candidates after they receive regulatory approval, this may lead to potentially significant negative consequences which include (i) withdrawal of approvals or revocation of licenses by regulatory authorities; (ii) suspension of marketing by us or our licensing partners; (iii) additional warnings required on the drug’s label; (iv) establishment of a risk evaluation and

RISK FACTORS

mitigation strategy, restricting distribution and imposing burdensome requirements; (v) the need for specific post-marketing studies; (vi) potential litigation and liability for harm caused to patients; and (vii) damage to our reputation. Further, combination therapy using our drug candidates together with third-party agents may involve unique AEs that could be exacerbated compared with AEs from monotherapies. Any of these events could prevent us or our licensing partners, as applicable, from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, financial condition, results of operations and prospects.

Initial, interim, top-line and preliminary data from our clinical trials that we may announce, observe or publish from time to time may change.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data. We also make assumptions, estimations, calculations and conclusions as part of our data analysis. As a result, the top-line or preliminary results that we report may differ from future results of the same studies and top-line data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more patient data become available or as patients from our clinical trials receive other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the [REDACTED] of our Shares after this [REDACTED].

The data and information we gather or otherwise rely on in our research and development process could be inaccurate or incomplete, which could harm our trial results, reputation and prospect.

We collect, aggregate, process, and analyze data and information from preclinical studies, clinical trials and other research and development programs. If mistakes are made in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer. These processes are governed by complex data processing and validation policies and regulations. We may be exposed to liability to a customer, court or governmental authority that concludes that our storage, handling, submission, delivery, or display of health information or other data is wrongful or erroneous.

In addition, we rely on third parties, including our collaborators, to collect, monitor and manage data for some of the ongoing preclinical and clinical programs for our drug candidates and have limited control over their activities. For instance, data from clinical trials conducted by our partner Inhibrx for ES102 in the United States may inform our clinical development of ES102 in China. If there are any inaccuracies, mistakes or incompleteness in the preclinical and clinical data of any of our collaborators, our clinical development activities may be negatively impacted as a result.

We may be unable to successfully develop or market our drug candidates or may experience significant regulatory delays, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates.

We plan to develop certain of our drug candidates for use as a combination therapy, which generally requires regulatory approval. For example, we obtained IND approvals from the NMPA for ES102 in combination with toripalimab in patients with advanced NSCLC in China. We also plan to develop ES104 both as a monotherapy and potentially in combination with chemotherapy. We may also seek to develop our drug candidates in combination with other drugs in the future. If the NMPA, the FDA or another comparable regulatory authority revokes its approval of such treatments or drugs we intend to use in combination with our drug candidates, we may not be able to market our drug candidates as a combination therapy as planned. If safety or efficacy issues arise

RISK FACTORS

with such treatments or drugs that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any drugs we use in combination with, we may not be able to complete clinical development of ES102 or other drug candidates as a combination therapy on our current timeline or within our current budget, or at all.

We invest substantial human and capital resources in research and development in order to develop our drug candidates and enhance our technologies, but we cannot guarantee that such efforts will lead to successful outcomes.

The global biopharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2024 and 2025, our research and development costs were RMB117.1 million and RMB105.6 million, respectively. We intend to continue to strengthen our technical capabilities in the development of our drug candidates, which requires substantial capital and time. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have not generated any revenue from the sales of approved drugs. Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate and the changing regulatory and market environments we encounter, may make it difficult to evaluate our prospects for future performance.

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Investment in the development of biopharmaceutical products is highly speculative as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we financed our operating activities primarily through bank borrowings and proceeds from equity financing. We have not generated any revenue from the sales of approved drugs to date, and we continue to incur significant research and development costs and other expenses related to our ongoing operations. As a result, we incurred net losses for the years ended December 31, 2024 and 2025 of RMB88.0 million and RMB154.8 million, respectively.

Substantially all of our net losses during the Track Record Period resulted from research and development costs, administrative expenses and fair value losses on convertible redeemable preferred shares. For details, see “Financial Information.” We expect to continue to incur net losses in the foreseeable future, and that these net losses may increase as we carry out certain activities relating to our development, including (i) ongoing and planned research and development activities; (ii) efforts to discover, develop, or in-license additional drug candidates and expand our product pipeline; (iii) scaling up our business to meet R&D, clinical trial, and commercialization requirements; (iv) hiring additional personnel for drug discovery, clinical, quality control, and administrative roles; (v) developing and protecting our intellectual property portfolio; (vi) seeking regulatory approvals for drug candidates; (vii) establishing sales, marketing, and distribution infrastructure; (viii) expanding operations globally; and (ix) incurring additional expenses related to operating as a public company. If any of our drug candidates fails during clinical trials or does

RISK FACTORS

not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and shareholders' equity.

We incurred net liabilities during the Track Record Period, and incurred net operating cash outflows for the year ended December 31, 2025, which may continue into the foreseeable future and expose us to liquidity risk.

We recorded net liabilities of RMB2,737.6 million and RMB2,883.5 million as of December 31, 2024 and 2025, respectively. A net liabilities position can expose us to liquidity and financial risks. This in turn could require us to seek financing from external sources such as debt issuance and bank borrowings, which may not be available on terms favorably or commercially reasonable to us, or at all.

Although we generated net cash from operating activities of RMB2.7 million for the year ended December 31, 2024, we had cash used in operating activities of RMB136.1 million for the year ended December 31, 2025 and may continue experiencing net cash outflows from our operating activities. Our forecast of the period of time through which our capital resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We expect to fund our future operations primarily with existing cash and cash equivalents, payments received from our license and collaboration agreements, and [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. As our business continues to expand, we may require further funding through equity offerings, debt financing, license and collaboration arrangements, and other sources. Changes in our ability to fund our operations may affect our cash flow and results of operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

Disruptions in the global financial markets and economic conditions could affect our ability to raise capital.

Global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors. In addition, concerns over the unrest and terrorist threats in the Middle East and Russian-Ukraine conflicts, among others, add uncertainties to the financial markets worldwide. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions in the long term.

RISK FACTORS

We have granted, and may continue to grant, certain awards under our share incentive plans, which may result in increased share-based compensation expenses.

We have adopted an employee stock option plan since 2019 for the purpose of granting share-based compensation awards to employees, officers, or directors to incentivize their performance and align their interests with ours (the “**2019 Share Incentive Plan**”). For the years ended December 31, 2024 and 2025, we incurred RMB21.4 million and RMB8.9 million, respectively, of share-based compensation expenses relating to awards granted under the 2019 Share Incentive Plan and restricted shares granted to our employees. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation awards to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may affect our financial condition and results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under the 2019 Share Incentive Plan from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following this [REDACTED].

We have historically received financial incentives, such as government subsidies, and we may not continue to receive such incentives in the future.

We have historically received various government subsidies, including subsidies from provincial and local PRC governmental authorities to support the research and development for our drug candidates and business operations. We recognized government grants as other income of RMB2.5 million and RMB2.0 million for the years ended December 31, 2024 and 2025, respectively. There is no assurance that we could continue to enjoy government subsidies at the historical levels, or at all. Any change, suspension or termination of these government subsidies, or government financial incentives in other forms, may have a negative impact on our business, financial condition and results of operations.

We enjoyed preferential tax treatment during the Track Record Period. Expiration of, or changes to, these incentives or policies, or our failure to satisfy any condition for these incentives, would have an adverse effect on our results of operations.

During the Track Record Period, Elpiscience Shanghai and Elpiscience Suzhou enjoyed a super deduction of 200% on qualified research and development costs. See “Financial Information — Description of Selected Components of the Consolidated Statements of Profit or Loss and Other Comprehensive Income — Income Tax Expense.” We cannot assure you that the PRC policies on preferential tax treatments will not change or that the current preferential tax treatments we enjoy or will be entitled to enjoy will not be canceled. If any such change, cancellation or discontinuation of preferential tax treatment occurs, the increase in our tax charge could materially and adversely affect our results of operations.

Fluctuations in exchange rates could result in foreign currency exchange losses.

The Renminbi has fluctuated against the U.S. dollar, at times significantly and unpredictably. We recorded net foreign exchange gains of RMB8.3 million for the year ended December 31, 2024 and net foreign exchange loss of RMB8.9 million for the year ended December 31, 2025, respectively. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. The [REDACTED] from the [REDACTED] will be received 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]. Furthermore, we are also required to complete filings with and obtain approvals from SAFE before converting significant sums of foreign

RISK FACTORS

currencies into Renminbi. All 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 Shares in foreign currency terms.

RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

The future commercial success of our drug candidates will depend on the degree of their market acceptance among physicians, patients, hospitals and others in the medical community.

Even if our drug candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance. Physicians and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs or drug candidates and may not become profitable. The degree of market acceptance of our drug candidates, if and only when they are approved for commercial sale, will depend on (i) the clinical indications for which they are approved; (ii) perceptions of their safety and efficacy by physicians, hospitals, and patients; (iii) the advantages over alternative treatments; (iv) the prevalence and severity of side effects; (v) product labeling and regulatory requirements; (vi) competitive market timing; (vii) treatment costs compared to alternatives; (viii) reimbursement availability from payors and authorities; (ix) patients' willingness to pay out-of-pocket expenses; (x) ease of administration compared to competitors; and (xi) the effectiveness of our sales and marketing efforts.

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

We have no experience in launching and marketing drug candidates. If we fail to establish, expand and optimize an effective sales and distribution network for our drugs, our business could be adversely affected.

Our operations to date have been largely focused on developing our drug candidates, and we have not demonstrated our ability to manufacture our drug candidates at a commercial scale or engage a third party to do so on our behalf, or to conduct sales, marketing and distribution activities necessary for the successful commercialization for our drug candidates. We intend to develop an in-house marketing and sales team, which will require significant capital expenditures, management resources and time. We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. We also plan to partnership with established commercial team externally for quick entries into the market. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that effective sales forces and network will be established. There can be no assurance that we will be able to develop in-house sales and marketing capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

The size of the potential market for our current or future drug candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual market opportunities for our current or future drug candidates may be smaller than our estimates.

There is no guarantee that any of our drug candidates, even if approved, would be approved for a first or second-line of therapy. As a result, even if we obtain significant market share for our drug candidates upon commercialization, we may not achieve significant revenue without obtaining regulatory approval for additional indications or as part of earlier lines of therapy. Our projections of both the number of people who have the cancers we are targeting, as well as the size of the patient

RISK FACTORS

population subset of people with these cancers in a position to receive first, second, third and fourth line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect.

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to unfavorable pricing regulations, which could harm our business.

Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. In China, the Ministry of Human Resources and Social Security of China, together with other government authorities, review the inclusion or removal of drugs from the National Reimbursement Drug List (the “NRDL”), regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs.

There can be no assurance that any of our future approved drug candidates will be included in the NRDL. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from the sales of approved drugs would be highly dependent on patient self-payment, which can make our products less competitive. Patients may choose other drugs with similar efficiency but lower price which have been included in the NRDL. Additionally, even if the Ministry of Human Resources and Social Security of China or any of its local counterparts were to accept our application for the inclusion of products in the NRDL, our potential revenue from the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL. In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process. Patients are unlikely to use any of our future approved drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs.

The manufacturing of biopharmaceutical products is a complex process, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.

We have limited experience in manufacturing biopharmaceutical products on a commercial scale, which is a complex process, in part due to strict regulatory requirements. We cannot assure you that issues relating to the manufacturing of our drug candidates will not occur in the future. We face additional manufacturing risks in relation to the CDMOs we engage for manufacturing activities. Issues may arise during the manufacturing process for reasons including: (i) equipment malfunction, (ii) failure to follow specific protocols and procedures, (iii) problems with raw materials, (iv) changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, (v) changes in the type of products produced, (vi) advances in manufacturing techniques, (vii) physical limitations that could inhibit continuous supply, and (viii) the occurrence of natural disasters. If problems arise during the production process of certain future products, a batch or several related batches of such product may have to be discarded and cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation.

We may not be able to maintain effective quality control over our drug products.

The quality of our products, including drug candidates we used for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance. We cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or

RISK FACTORS

deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, and/or harm our market reputation and relationship with business partners.

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

The illegal importation of competing products from countries where government price regulation or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China, the United States and other countries and regions where we commercialize our products in the future. Furthermore, certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Our reputation and business could suffer as a result of counterfeit or unauthorized pharmaceutical products sold under our or our collaborators’ brand name(s).

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We have entered into license and collaboration arrangements and may form or seek strategic partnerships or enter into similar arrangements in the future, and we may not realize the benefits of such partnerships or arrangements as expected.

We may from time to time form or seek strategic partnerships, enter into licensing arrangements or establish other collaborative relationships with third parties that we believe will complement or augment our R&D and commercialization efforts with respect to our drug candidates. For details, see “Business — License and Collaboration Arrangements.”

We cannot assure you that we will be able to maintain our relationships with our licensing partners or that we will be able to renew our existing agreements when they expire. Our failure to maintain such relationships or obtain such renewals could materially and adversely affect our operations, revenue and profitability. Reduction or elimination of our rights under such agreements may force us to negotiate new or restated agreements with less favorable terms, or cause disruptions to our ongoing activities carried out in reliance of such rights, including our rights to important intellectual properties and technologies. The continuous collaboration under these license agreements is subject to both parties’ performance of their contractual obligations, the achievement of certain milestones, such as regulatory approvals, and each party’s decision to carry on or terminate the collaboration in light of various circumstances, all of which could materially affect our business and operations. For example, in February 2024, Inhibrx and us decided to terminate one of our collaboration programs, ES101/INBRX-105, after evaluation of the totality of the data from the drug candidate’s clinical trials, and we cannot guarantee that similar decisions will not be made by us or our business partners in the future.

Collaborations involving our drug candidates are subject to specific risks including: (i) collaborators having discretion over the resources and efforts they apply; (ii) collaborators ceasing or delaying development due to strategic changes, acquisitions, or funding issues; (iii) delays, insufficient funding, or discontinuation of clinical trials; (iv) collaborators developing competing drugs; (v) improper maintenance or defense of intellectual property rights; (vi) lack of cooperation or responsiveness in clinical trials; (vii) disputes that cause delays, termination, or costly litigation; and (viii) shared ownership of intellectual property, limiting exclusivity. Furthermore, we face significant competition in seeking appropriate strategic partners with whom we collaborate to develop our drug candidates, and the negotiation process is time-consuming and complex.

RISK FACTORS

We rely on third parties to monitor, support and/or conduct clinical trials and preclinical studies of our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially affected.

We have relied on and plan to continue to rely on third-party CROs to monitor and manage data for some of our ongoing preclinical and clinical programs. CROs may fail to meet regulatory standards or contractual obligations, which could result in unreliable data and delays in approval. Our collaboration with CROs may be terminated for material breaches, or under other circumstances with or without our consent, and transitioning to new CROs may cause delays and data issues.

Notwithstanding the remedies available to us under our agreements with our CROs, we cannot control whether or not such CROs will devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If any of our CROs fail to comply with the applicable GCP, GLP, cGMP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. There can be no assurance the regulatory authorities will determine that our clinical trials comply with all the applicable requirements which may lead us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

We rely on third parties to manufacture our drug products for clinical development and commercial sales. Our business could be harmed if these third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality or price levels.

We have limited experience in managing the manufacturing process and also rely on third-party vendors to manufacture our drug candidates. See “Business — Manufacturing” for details. We have not yet manufactured or processed our drug candidates on a commercial scale. However, our anticipated reliance on third-party manufacturers exposes us to certain risks, including: (i) difficulty identifying manufacturers that meet acceptable terms, as they must be approved by regulatory authorities; (ii) limited manufacturing capacity or slots that may delay production timelines; (iii) required process improvements after inspections that may affect production schedules; (iv) inability to meet clinical or commercial quantity and quality requirements; (v) failure to execute manufacturing procedures or logistical support; (vi) termination of agreements by contract manufacturers; (vii) difficulty sourcing raw materials and products from certain manufacturers; and (viii) supply interruptions due to inclement weather or disasters.

The quality of our products manufactured by contract manufacturers will depend significantly on the effectiveness of our quality control and quality assurance and that of our contract manufacturers. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, jeopardize our drug approvals or licenses and/or harm our market reputation and relationship with business partners.

We depend on third parties to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. Any interruptions of or significant price increases in such supply could adversely affect our business.

During the Track Record Period, we relied on third parties to supply certain raw materials and products used in our research and development and clinical trials. Disruptions or inadequate supply could impair our operations and R&D, and increased costs could lower our profitability. Despite quality inspections, we cannot guarantee all issues will be identified and resolved. Non-compliance by suppliers could lead to delays, regulatory issues, product liability claims, and significant costs, adversely affecting our business.

RISK FACTORS

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

Our relationships with principal investigators, physicians and other industry experts play an important role in our research and development and marketing activities. We cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to the successful development and marketing of drug candidates.

If our business partners fail to maintain the necessary licenses for the development, production, promotion, sales and distribution of our drug candidates, our business, financial condition and results of operations could be adversely affected.

Our business partners, such as CROs, CDMOs and suppliers, on whom we may rely on to develop, manufacture, market, sell and distribute our drug candidates, may be subject to requirement of obtaining and maintaining necessary permits, licenses and certificates in their operations. If our business partners fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Our license agreements may impose development obligations and fees based on milestones. Failure to comply could result in termination of the license, adversely affecting our ability to commercialize drug candidates. We may rely on sublicenses from third parties, where we have no relationship with the original licensor. Failure by licensors to comply may result in termination of the sublicense, and losing sublicenses or failing to secure direct licenses could affect our ability to develop and commercialize drug candidates. Disputes may arise regarding intellectual property subject to a licensing agreement, including: (i) the scope of rights granted and related interpretation issues; (ii) the amount and timing of payments owed; (iii) potential infringement of the licensor’s intellectual property; (iv) sublicensing of patent and other rights in future collaborations; (v) our diligence obligations and what activities fulfill them; (vi) ownership of inventions and know-how resulting from joint creation or use; and (vii) priority of invention of patented technology. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain any licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates.

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

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important primarily by filing patent applications in China, the U.S. and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. As of the Latest Practicable Date, we owned nine approved patents, and had filed 90 patent applications in China,

RISK FACTORS

the U.S., and other jurisdictions, and under the PCT (including PCT patent applications that have entered national phase, pending PCT applications which may enter various contracting states in the future, and PCT applications which were filed as priority applications). This process is costly and time-consuming, and we may not be able to secure protection in all jurisdictions or identify patentable aspects of our research in time. Additionally, we may fail to detect third-party infringement or take appropriate action to enforce our rights.

The patent position of biopharmaceutical companies generally involves complex legal and factual questions, and can be frequently litigated. The validity, scope, and enforceability of our patents are uncertain, and our patent applications may not prevent third parties from commercializing competing technologies. The examination process may narrow the scope of our patents, and prior art may invalidate patents or prevent them from being granted. Even if patents are issued, third parties may challenge their validity or scope, potentially narrowing or invalidating our patent claims. This could allow competitors to commercialize similar technologies and drug candidates, undermining our ability to compete effectively.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business nor permit us to maintain our competitive advantage. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in any jurisdictions. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Our competitors may also be able to circumvent our patent issuance by developing similar or alternative technologies or drug candidates in a non-infringing manner.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated for noncompliance with these requirements. In addition, if our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

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

We own a number of trademarks in China and other jurisdictions. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks, and may not be registered in all the necessary or desirable jurisdictions and categories in which we intend to sell our future products or provide our future services. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We also may be subject to claims that our employees, consultants, or advisers 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.

In addition to our issued patents and pending patent applications, we rely on trade secret and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. If we collaborate with third parties for the development of our current or any future drug candidates, we must, at times, share trade secrets with them. Despite our efforts to protect our trade secrets, our

RISK FACTORS

competitors may discover our trade secrets. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, and results of operations.

Furthermore, many of our employees, consultants, and advisers, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. 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. Litigation may be necessary to defend against these claims. 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, be a distraction to our management and scientific personnel and have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property in general, thereby impairing our ability to protect our current and any future drug candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in China, the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, there are periodic proposals for changes to the patent laws in China, the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology.

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

We cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Many third-party patents exist in the fields we are working in, and we may face allegations of infringement or misappropriation. Patent litigation is common in the biopharmaceutical industry, and some claimants may have more resources to sustain prolonged litigation. We may fail to identify relevant patents or patent applications, and the publication of patents often lags behind discoveries. Our drug candidates may also infringe patents issued in the future, potentially affecting our ability to commercialize them.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Defending these claims could result in substantial costs, and we may be forced to settle, potentially paying royalties or licensing fees. Even if we secure a license, it may be non-exclusive, allowing competitors access to the same intellectual property. Furthermore, despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. Courts may invalidate patents or fail to grant injunctions against infringers, and any loss of intellectual

RISK FACTORS

property protection could harm our business. Additionally, defending intellectual property rights could lead to counterclaims, requiring substantial resources. An adverse result in any litigation or defense proceedings could put one or more of our intellectual property rights at risk of being invalidated or interpreted narrowly. Public announcements of negative outcomes could also affect [REDACTED] perception and the value of our shares.

RISKS RELATING TO GOVERNMENT REGULATIONS

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

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to implement a global development strategy, with a focus on China and the United States, the two largest pharmaceutical markets in the world. The process of obtaining regulatory approvals and compliance with appropriate laws, regulations and guidance requires the expenditure of substantial time and financial resources. In many countries or regions where a drug is intended to be ultimately sold, including China and the U.S., the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. Any action against us for violation of the relevant laws, regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and adversely affect our reputation and financial results.

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

Generally, approval from the NMPA and FDA take many years to obtain, following the commencement of preclinical studies and clinical trials. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes. Our drug candidates could fail to receive the regulatory approval of the NMPA, the FDA or a comparable regulatory authority due to: (i) disagreements over clinical trial design or implementation; (ii) inability to demonstrate safety, efficacy, or potency for the proposed indication; (iii) failure to meet statistical significance in clinical trial results; (iv) non-compliance with GCP inspections; (v) inability to prove clinical benefits outweigh safety risks; (vi) disagreement over data interpretation; (vii) insufficient data to support submissions for approval; (viii) failure to pass cGMP inspections; (ix) failure of clinical sites to pass audits; (x) deficiencies in manufacturing; (xi) changes in approval policies that affect data sufficiency; and (xii) failure to adapt to scientific or technological advancements required by regulations.

The NMPA, the FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

RISK FACTORS

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses.

If the NMPA, the FDA or other comparable regulatory authorities approve any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any CMC, variations, continued compliance with current cGMPs, and GCPs and potential post-approval studies for the purposes of license renewal. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to other conditions of approval, including requirements for potentially costly post-marketing studies, such as studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved by the NMPA, the FDA or other comparable regulatory authorities for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes. If any of the foregoing occurs with respect to our drug products, it may result in: (i) restrictions on marketing or manufacturing, withdrawal from the market, or recalls; (ii) fines, warning letters, or holds on clinical trials; (iii) refusal by regulatory authorities to approve applications or supplements, or suspension/revocation of drug licenses; (iv) refusal to accept IND, NDA, or BLA approvals; (v) drug seizure, detention, or refusal of import/export; and (vi) injunctions or civil, administrative, or criminal penalties. Moreover, regulations or policies may change or additional government regulations may be finalized that could prevent, limit or delay regulatory approval of our drug candidates. Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity.

Changes in laws and regulations relating to the biopharmaceutical industry, including the ongoing healthcare reform in China, may result in additional compliance risks and costs.

In China, the U.S. and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes relating to the biopharmaceutical industry and the healthcare system. In particular, the PRC government has enacted a series of new laws and regulations in recent years aimed at improving the affordability and deterring potential over-use of oncology drugs. These new laws, regulations and healthcare reform measures and others which may be adopted in the future may result in more rigorous prescription and coverage criteria, new reimbursement methods and additional downward pressure on drug prices.

Although none of our drug candidates had been commercialized as of the Latest Practicable Date, these legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our drug candidates in the future. Moreover, because these laws and regulations are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing changes regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices.

Any failure to maintain governmental licenses or permits could jeopardize our reputation and business.

We are required to obtain and maintain certain licenses and permits for conducting our business. If any regulatory authorities consider that we were operating without the requisite approvals, licenses or permits or promulgates new laws and regulations that require additional approvals or licenses or imposes additional restrictions on the operation of any part of our business, it has the power, among other things, to levy fines, confiscate our income, revoke our business licenses, and require us to discontinue our relevant business or impose restrictions on the affected portion of our business.

RISK FACTORS

If our CROs, CDMOs and other business partners fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties and other negative consequences that could have a material and adverse effect on the success of our business.

We and certain third parties we work with, such as our CROs, CDMOs and business partners, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We cannot guarantee our contractors could continuously maintain their qualifications with regard to such disposal. 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. We may also incur liabilities due to injuries to our employees resulting from the use of or exposure to hazardous materials, and we do not maintain insurance covering such potential liabilities. 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 affect our research, development or production efforts.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China, the U.S. and other jurisdictions, which could increase our compliance costs or even expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational damage and diminished profits and future earnings.

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the approval for any of our drug candidates and begin commercializing our drugs in China in the future, our operations may become subject to various PRC fraud and abuse laws. These laws may impact, among others, our proposed sales, marketing and education programs. Furthermore, we are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. In addition, although currently our business operations are primarily in China, we are subject to the Foreign Corrupt Practices Act (FCPA) of the United States, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

As we expand our operations globally, we may also become subject to similar laws and regulations from other jurisdictions. There are ambiguities as to what is required to comply with any of these laws and regulations. If any of the physicians or other third parties with whom we do business are found to be not in compliance with the applicable laws and regulations, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We face regulation and potential liability related to privacy, data protection and information security which may require significant resources and may adversely affect our business, operations and financial performance.

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

RISK FACTORS

The personal information of patients or subjects which might be involved in our clinical trials might be sensitive and we are subject to strict requirements under the applicable privacy protection regulations in the relevant jurisdictions. While we have adopted security policies and measures to protect our proprietary data and patients’ privacy, such policies and measures might not satisfy the all the requirements in every respect under the applicable laws and regulations. Data leakage and abuse and other misconduct related to data and personal information protection might not be completely avoided, due to hacking activities, human error, employee misconduct or negligence or system breakdown, among other reasons. We also cooperate with hospitals, CROs and other business partners, licensors, contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure.

We may be restricted from transferring our scientific data abroad or using human genetic resources collected in China.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which provides that enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent any data collected or generated in connection with our R&D of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China.

In addition, the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) (the “**HGR Regulation**”), which was promulgated on May 28, 2019 and further amended on March 10, 2024, stipulates that foreign organizations, foreign individuals and the institutions established or actually controlled thereby shall not collect or preserve China’s human genetic resources within the PRC, and shall not be provided with China’s human genetic resources unless certain procedures required thereunder have been completed. Among others, for example, where human genetic resource information is provided or made available to a foreign organizations or an institution established or actually controlled by the foreign organization or foreign individual, it shall be filed with the health department of the State Council, with such human genetic resource information submitted for backup. See also “Regulatory Overview — PRC Regulations — Regulations on Clinical Trials and Registration of Drugs — Approval of Human Genetic Resources.” During the Track Record Period and up to the Latest Practicable Date, as advised by our PRC Legal Adviser, no instances had been identified where we provided human genetic resource information to foreign entities in violation of the HGR Regulation, and we had not been subject to any administrative penalties under the HGR Regulation for such activities during the same period.

Moreover, the regulatory framework on cross-border transfer of personal information and data worldwide is rapidly evolving. For example, in recent years, China has promulgated several laws and regulations on cross-border data transfer, including but not limited to the Cybersecurity Law (《網絡安全法》), the Data Security Law (《數據安全法》), the Personal Information Protection Law (《個人信息保護法》) and the Provisions on Facilitating and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》). These regulations have provided that, amongst others, critical information infrastructure operators that provides any personal information or important data to an overseas recipient, and other data processors that provides any important data, sensitive personal information and certain amount personal information shall be subject to security assessment, standard contract or personal information protection certification for outbound data transfer activities, unless otherwise provided under the relevant laws and regulations. Our

RISK FACTORS

subsidiary in the U.S. has ceased to conduct R&D activities since 2023 and was not involved in any cross-border data transfer activities during the Track Record Period and up to the Latest Practicable Date. In anticipation of providing the clinical data that we collected and stored from clinical trials conducted in China and/or regulated by the NMPA to overseas recipients outside China for R&D, collaboration and other purposes, we have completed the filing of the Standard Contract for the Cross-border Transfer of Personal Information with the Cyberspace Administration of China pursuant to relevant PRC laws and regulations, which permits the transfer of clinical trial data from China to overseas regulatory authorities, affiliates and collaborating partners, including, among others, the FDA. However, the relevant rules or regulations promulgated may impose additional compliance requirements, including any approval, filing and other administrative measures thereunder.

Changes in the political and economic policies, as well as the interpretation and enforcement of laws, rules and regulations, may affect our business, financial condition, results of operations and prospects.

A substantial portion of our operations are based in the PRC, our business, financial condition, results of operations and prospects may be affected by economic, political, social and legal developments in China. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources; however, we cannot guarantee the extent to which our business operations will be able to benefit from such measures, if at all. In addition, laws, rules and regulations may also be amended from time to time, and the application, interpretation and enforcement of such evolving laws, rules and regulations may affect our business operations. Any of the foregoing may have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may be classified as a “PRC resident enterprise” for PRC enterprise income tax purposes, and our income may be subject to PRC tax under the relevant PRC laws.

Under the Enterprise Income Tax Law (the “EIT Law”), an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it will be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. For details, see “Regulatory Overview — PRC Regulations — Regulations on Taxation.” If the PRC tax authorities determine that we or any of our subsidiaries incorporated out of the PRC is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules, Circular 82 and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by PRC enterprise would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to any withholding tax. Finally, the EIT Law and its implementing rules issued by PRC tax authorities provide that dividends paid by us to our non-PRC shareholders and, while less clear, capital gains recognized by them with respect to the sale of our Shares may be subject to tax of 10% for non-PRC resident enterprise shareholders and 20% for non-PRC resident individual shareholders. In the case of dividend payments, such PRC tax may be withheld at source.

PRC regulations on loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make loans or additional capital contributions to our PRC subsidiaries.

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of the SAFE. Additionally, if we finance such subsidiary by means of additional capital contributions, these capital contributions must be registered, reported or filed with certain government authorities, including the MOFCOM, the SAMR and the SAFE or their local counterparts. We cannot assure you that we

RISK FACTORS

will be able to obtain these government registrations or approvals or to complete registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our subsidiaries or any of their respective subsidiaries. If we fail to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected.

We may rely on dividends and other distributions on equity paid by our subsidiaries to fund any cash and financing requirements we may have. Any limitation on the ability of our subsidiaries to make payments to us could have a material adverse effect on our ability to conduct our business or financial condition.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity that may be paid by our subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to the holders of our Shares and service any debt we may incur. If any of our subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other distributions to us.

Failure to comply with PRC regulations regarding the registration requirements for employee share ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In 2012, the SAFE, promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》). Pursuant to these rules, PRC citizens and non-PRC citizens who reside in China for a continuous period of not less than one year and participate in any stock incentive plan of an overseas publicly listed company are required to register with SAFE through a domestic qualified agent, which could be the PRC subsidiaries of such overseas-listed company. Failure to complete SAFE registrations may subject them or us to fines or supervision measures. We also face regulatory changes that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees. In addition, the STA has issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in China who exercise share options or are granted restricted shares will be subject to PRC individual income tax. Our PRC subsidiary has obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes for those employees who exercise their share options. If our employees fail to pay or we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities.

We are subject to filings and other requirements from the CSRC or other PRC regulatory authorities for the [REDACTED] and any further capital raising activities.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures have comprehensively improved and reformed the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities. Any such domestic company that is deemed to conduct overseas offering and listing activities, including both the [REDACTED] and any further capital raising, shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

RISK FACTORS

We will file with the CSRC within the specific time limit as required by the Overseas Listing Trial Measures and seek guidance from the relevant regulator and/or our legal advisers to ensure our compliance in all respects. In addition, it is uncertain whether we can or how long it will take us to complete such filings. Any failure to complete such filings may impede the [REDACTED] and may subject us to sanctions by the CSRC or other PRC government authorities. Furthermore, such failure may adversely affect our ability to finance the development of our business and may have a material adverse effect on our business and financial condition.

RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to attract, retain and motivate senior management, qualified medical professionals and scientific employees.

Recruiting, retaining and motivating qualified management, scientific, clinical and sales and marketing personnel are critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

Our future financial performance and our ability to commercialize our drug candidates will also depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies. For details, see “Business — Our Development Strategies.” Our development endeavors will require substantial management attention and efforts and significant additional expenditures. If we fail to expand at our expected pace, we may face capacity constraints in the future which may adversely affect our business and financial condition.

Our potential engagement in acquisitions or strategic partnerships may increase our capital requirements, dilute the value of your [REDACTED] in our Shares, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring drug candidates and technologies, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: (i) increased operating expenses and cash requirements; (ii) assumption of additional indebtedness or liabilities; (iii) issuance of equity securities; (iv) challenges in assimilating operations, intellectual property, products, and personnel; (v) diversion of management’s attention from existing programs; (vi) retention of key employees and maintaining business relationships; (vii) risks associated with the counterparty’s prospects and products; (viii) inability to generate sufficient revenue from acquired technology or products; and (ix) changes in accounting principles impacting financial results.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

RISK FACTORS

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

From time to time, we, our management or directors may be involved in inspections, claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, privacy protection, environmental and safety matters, breach of contract, employment or labor disputes and intellectual property rights. Any inspections, claims, disputes or legal proceedings initiated by us or brought against us, our management or directors, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation.

Our reputation is important to our success. Negative publicity with respect to us, our management, employees, business partners, affiliates, or our industry, may materially and adversely affect our reputation, business, results of operations and prospect.

Our reputation is crucial to our business success, but it is vulnerable to threats that can be difficult to control. Engaging third parties to expand our commercialization network may make it harder to manage our brand reputation. Regulatory inquiries or allegations of unethical conduct by us, our management, employees, or affiliates could harm our reputation and adversely affect our business. Such damage to our reputation could hinder our ability to attract talent, business partners, and grow our business.

We may be exposed to risks of conducting our business and operations in international markets.

Overseas markets are an important component of our growth strategy. We plan to explore market opportunities overseas, where we believe there is substantial demand for our drug candidates, and we intend to identify and collaborate with reputable local partners that have proven track record to maximize the global value of our drug candidates. We will also continue to seek licensing and co-development opportunities with global MNCs, and expand our global clinical programs. For more details, see “Business — Our Development Strategies.”

However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including: (i) increased expenses or diverted management attention due to collaboration or licensing arrangements; (ii) changes in political, cultural, or economic conditions in specific regions; (iii) differing regulatory requirements for drug approvals internationally; (iv) difficulty enforcing contracts in local jurisdictions; (v) reduced protection for intellectual property rights; (vi) unexpected changes in tariffs, trade barriers, and regulations; (vii) compliance with tax, employment, immigration, and labor laws for employees abroad; and (viii) business interruptions due to geopolitical actions or natural disasters. These and other risks may materially adversely affect our ability to attain or sustain revenue and profits from international markets.

Increased labor costs could slow our growth and adversely affect our operations and profitability.

Our operations depend in part on the skills and know-how of our employees. We cannot assure you that there will not be increase in labor cost, which may adversely affect our operations and financial condition. In addition, share options and other share-based incentives granted under our existing or future share-based incentive arrangements and scheme could adversely affect our costs and our results of operations.

RISK FACTORS

We may be subject to additional social insurance fund and housing provident fund contributions and late fees or fines imposed by relevant regulatory authorities.

Pursuant to the Chinese laws and regulations, we are required to participate in the employee social welfare plan administered by local governments. During the Track Record Period, we did not pay social insurance and housing provident fund for a few foreign employees. As the PRC rules have provided that we, subject to a few exceptions, have to pay social insurance for our foreign employees, we may be required by competent authorities to pay the outstanding amount, and may be subject to late payment penalties or enforcement application made to the court. Based on the relevant rules and regulations, the shortfall of social insurance amounted to approximately RMB0.4 million and RMB0.4 million for the years ended December 31, 2024 and 2025, respectively. According to the Social Insurance Law, if an employer fails to make social insurance contributions in full, the relevant authorities could order the employer to pay, within a prescribed time limit, the outstanding amount with an additional late payment penalty at the daily rate of 0.05%, and if the employer fails to make the overdue contributions within such time limit, a fine equal to one to three times the outstanding amount may be imposed. Additionally, according to the Regulation on the Administration of Housing Provident Fund, if the employer fails to register and establish an account for an employee’s housing provident fund contributions, the authority could order the employer to correct it within a prescribed time limit, where failure to do so at the expiration of the time limit shall result in a fine between RMB10,000 and RMB50,000 being imposed. Where an employer is overdue in the payment and deposit of, or underpays, the housing provident fund, the authority could order it to make the payment and deposit within a prescribed time limit, and where the payment and deposit has not been made after the expiration of the time limit, an application may be made to a court in China for compulsory enforcement. As of the Latest Practicable Date, no competent government authorities imposed administrative action, fine or penalty to us with respect to this non-compliance incident or required us to settle the outstanding amount of social insurance payments and housing provident fund contributions. We cannot guarantee you that the competent government authorities will not require us to settle the outstanding amount within the specified time limit or impose late payment penalties on us. Such actions may have a material and adverse impact on our financial position and results of operation.

Changes in international trade policies and political tensions may adversely impact our business and results of operations.

We are susceptible to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. Tensions and political concerns between China and other countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. China’s political relationships with foreign countries and regions may affect the prospects of our relationship with third parties, such as business partners, suppliers and future customers. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may cause a decline in the demand for our future products and adversely affect our business, financial condition, results of operations, cash flows and prospects.

Rising trade and political tensions could reduce levels of trades, investments, technological exchanges and other economic activities between China and other countries and regions, which would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies. The imposition of tariffs and other trade restrictions by the U.S. and other jurisdictions could disrupt cross-border operations and global supply chains. For example, beginning in February 2025, the U.S. government implemented increased tariffs on certain Chinese imports across multiple sectors, to which China responded with retaliatory tariffs on U.S. goods. These measures led to periods of escalating trade tensions, including instances where tariff rates reached triple-digit levels. While the U.S. and China announced temporary trade agreement in October 2025 following bilateral negotiations, which included partial tariff reductions, the

RISK FACTORS

long-term stability of these measures remains uncertain. We cannot predict how tariff policies in the U.S. and other countries may further evolve or anticipate the full impact of subsequent developments in such policies on our business.

While we have not started commercialization of drug candidates, any rising trade and political tensions or unfavorable government policies on international trade, such as capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. In particular, if any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition and results of operations. In addition, our results of operations could be adversely affected if any such tensions or unfavorable government trade policies harm the Chinese economy or the global economy in general.

During the Track Record Period and up to the Latest Practicable Date, as advised by our legal advisors, we had not been affected by the abovementioned geopolitical tensions in any material respect, considering that (i) all our drug candidates remain in the development stage and we had not generated any revenue from the sales of commercialized products; (ii) we did not procure any raw materials directly from the United States, and all of our five largest suppliers during each year of the Track Record Period were based outside the United States (primarily in China and, to a lesser extent, Australia); and (iii) the scale of R&D activities conducted by our subsidiary in the United States, Elpiscience U.S. currently represents a negligible portion of our overall operations. For the years ended December 31, 2024 and 2025, our research and development costs attributable to Elpiscience U.S. were RMB1.7 million and RMB1.9 million, respectively. However, there is no assurance as to how the U.S.-China trade disputes and other tensions might develop or whether there will be any changes to the scope and extent of businesses that will be subject to such tariffs, sanctions and export controls, and restrictive measures.

In addition, we or our business partners, including our CDMOs, may become subject to the recently enacted BIOSECURE Act aiming at discouraging federal contracting with entities that use biotechnology equipment or services provided by certain Chinese biotechnology companies. If we or our business partners were to be listed as or designated as “biotechnology companies of concern,” our ability and our business partners’ ability to engage in business with the U.S. government or with companies that engage in business with the U.S. government may be limited, which could disrupt or diminish our business activities. Any delay in identifying and entering into commercially reasonable business relationship with a new partner could harm our ability to develop products on time or within budget, which could materially adversely affect our business, financial condition and results of operations.

On February 21, 2025, U.S. President Donald J. Trump issued a memo entitled the “America First Investment Policy” (the “America First Memo”), outlining the ongoing review and consideration of potential new or expanded restrictions on U.S. outbound investment in the PRC in sectors such as biotechnology, hypersonics, aerospace, advanced manufacturing, and directed energy. The America First Memo also contemplates potential restrictions on investments in publicly traded securities by pension funds, university endowments and other limited partner investors. Such political tensions and policy changes could have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies, which may in turn affect our business and results of operations in the future.

RISK FACTORS

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

Natural disasters, health epidemics, acts of war or 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. The occurrence of a disaster or a prolonged outbreak of an epidemic illness, including COVID-19, or other adverse public health developments in which we operate our business could materially disrupt our business and operations. These uncertain and unpredictable factors include, but are not limited to, adverse effects on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners and CROs. As COVID-19's global impact continued to lessen as of the Latest Practicable Date, our Directors do not expect COVID-19 to have a material adverse impact on our business going forward. However, our results of operations in the future may be influenced by COVID-19's evolving patterns and associated market developments.

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

We maintain industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. 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. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. In line with general market practice, we have elected not to maintain certain types of insurances, such as business interruption insurance or key personnel life insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct by our employees or third parties. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business, results of operations and reputation.

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

Despite the implementation of security measures, our information technology systems and those of our CROs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

RISK FACTORS

Our risk management and internal control systems may not be thorough or effective in all respects.

Due to the inherent limitations in the design and implementation of risk management and internal control systems, we cannot assure that our risk management and internal control systems will be able to identify, prevent and manage all risks. Our internal procedures are designed to monitor our operations and ensure their overall compliance. However, it is not always possible to timely detect and prevent fraud and other misconduct committed by our employees or third parties, and the precautions we take to prevent and detect such activities may not be effective. Furthermore, we cannot assure you that our risk management and internal control systems will be effectively implemented. If we fail to adapt our risk management policies and procedures to our evolving business in a timely manner, our business, financial condition and results of operations could be materially and adversely affected.

Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them.

We have leased certain properties in China as our offices and R&D facilities. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases.

As of the Latest Practicable Date, we had not completed lease registration for one of our leases in Suzhou with an aggregate GFA of 50 square meters. See also “Business — Properties.” Although failure to register does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future. Any dispute or claim in relation to these properties, including the lessors’ alleged unauthorized lease of these properties, could force us to relocate these properties. If any of our leases is terminated or becomes unenforceable as a result of challenges from third parties, we would need to seek alternative properties and incur relocation costs. Any relocation could lead to disruptions to our operations and adversely affect our business, financial conditions and results of operations.

We operate in both civil and common law systems and the legal protection available might differ in different jurisdictions.

Our operating subsidiary and operations are mainly located in the PRC. Our business in the PRC is subject to the PRC laws and regulations applicable to foreign investment in the PRC. The PRC legal system is a civil law system based on written statutes. Unlike the common law legal system, prior court decisions in a civil law system might have little precedential value and can only be used as a reference. Moreover, we cannot predict the effect of future developments in the legal systems and regulatory structures of China, the U.S. and other regions we might have business. Such unpredictability towards our contractual, property and procedural rights as well as any changes to our rights licensed, approved or granted by the competent regulatory authority could adversely affect our business and impede our ability to continue our operations.

RISK FACTORS

You may experience difficulties in effecting service of process upon or enforcing foreign judgments against us or our Directors or officers.

Most of our assets are situated in the PRC and most of our directors and officers reside in the PRC. Therefore, there remains the possibility that it may be difficult to effect service of process outside the PRC upon most of our directors and officers, including with respect to matters arising under applicable securities laws. The PRC does not have treaties providing for the reciprocal recognition and enforcement of civil case judgments of courts with the United States and some other countries. Consequently, you may experience difficulties in enforcing against us or our directors or officers in the PRC any judgments obtained from courts outside of the PRC. On January 18, 2019, the Supreme People’s Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), which has come into effect on January 29, 2024 and seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However, we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] for our Shares prior to the [REDACTED]. An active [REDACTED] for our Shares may not develop or be sustained.

Prior to the completion of the [REDACTED], there has been no [REDACTED] for our Shares. There can be no guarantee that an active [REDACTED] for our Shares will develop or be sustained after completion of the [REDACTED]. The [REDACTED] is the result of negotiations between our Company and the [REDACTED] (for themselves and on behalf of the [REDACTED]), which may not be indicative of the [REDACTED] at which our Shares will be [REDACTED] following completion of the [REDACTED]. The [REDACTED] of our Shares may drop below the [REDACTED] at any time after completion of the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED] the Share. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will not decline following the [REDACTED].

The [REDACTED] and [REDACTED] of our Shares may be [REDACTED]. You may not be able to resell our Shares at or above the [REDACTED] you pay, or at all.

The [REDACTED] and [REDACTED] and of our Shares may be [REDACTED] and could fluctuate widely in response to factors beyond our control, including general market conditions of the securities markets in Hong Kong, China, the United States and elsewhere in the world. In particular, the performance and fluctuation of the [REDACTED] of other companies with business operations located mainly in China that have listed their securities in Hong Kong may affect the [REDACTED] in the [REDACTED] of and [REDACTED] for our Shares. A number of China-based companies have listed their securities, and some are in the process of preparing for listing their securities, in Hong Kong. Some of these companies have experienced significant volatility. The trading performances of the securities of these companies at the time of or after their offerings may affect the overall investor sentiment towards China-based companies listed in Hong Kong and consequently may impact the [REDACTED] of our Shares. These broad market and industry factors may significantly affect the [REDACTED] and [REDACTED] of our Shares, regardless of our actual operating performance, and may result in losses on your [REDACTED] in our Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] for

RISK FACTORS

our Shares maybe highly [REDACTED] for specific business reasons. In particular, factors such as variations in our revenue, earnings, and cash flow could cause the [REDACTED] of our Shares to change substantially. Any of these factors may result in large and sudden change in the [REDACTED] and [REDACTED] of our Shares.

The actual or perceived sale or availability for sale of substantial amounts of our Shares, especially by our directors, executive officers and substantial Shareholders, could adversely affect the [REDACTED] of our Shares.

Future sales of a substantial number of our Shares, especially by our directors, executive officers and existing Shareholders, or the perception or anticipation of such sales, could negatively impact the [REDACTED] of our Shares in Hong Kong and our ability to raise equity capital in the future at a time and price that we deem appropriate. The Shares held by our existing Shareholders are subject to certain lock-up periods. See “[REDACTED].” While we currently are not aware of any intention of such persons to dispose of significant amounts of their Shares after the expiry of the lock-up periods, we cannot assure you that they will not dispose of any Shares they may own now or in the future. The effect of such disposal, if any, on the [REDACTED] of the Shares cannot be predicted.

You will incur immediate and substantial dilution and may experience further dilution if we [REDACTED] additional Shares in the future.

As the [REDACTED] of Shares is higher than the net tangible book value per share of our Shares immediately prior to the [REDACTED], [REDACTED] of our Shares in the [REDACTED] will experience an immediate dilution. If we [REDACTED] additional Shares in the future, [REDACTED] of our Shares in the [REDACTED] may experience further dilution in their shareholding percentage.

We cannot assure you that we will declare and distribute any amount of dividends in the future.

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we have not yet adopted a dividend policy with respect to future dividends. Therefore, you should not rely on an [REDACTED] in our Shares as a source for any future dividend income. Our Board has discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our Company may pay dividends out of profits or share premium, provided always that in no circumstances may a dividend be paid out of share premium if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiary, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your [REDACTED] in our Shares will likely depend entirely upon any future [REDACTED] appreciation of our Shares. There is no guarantee that our Shares will appreciate in value or even maintain the [REDACTED] at which you [REDACTED] the Shares. You may not realize a return on your [REDACTED] in our Shares and you may even lose your entire [REDACTED] in our Shares.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations, the [REDACTED] and [REDACTED] may decline.

The [REDACTED] for our Shares will be influenced by research or reports that industry or securities analysts publish about us or our business. If one or more analysts who cover us downgrade our Shares or publish negative opinions about us, the [REDACTED] for our Shares would likely decline regardless of the accuracy of the information. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the [REDACTED] or [REDACTED] of our Shares to decline.

RISK FACTORS

The industry facts, statistics and forecasts in this document that were obtained from various government publications have not been independently verified.

This document, particularly the section headed “Industry Overview,” contains information and statistics relating to the healthcare market. Such information and statistics have been derived from third-party reports, either commissioned by us or publicly accessible, and other publicly available sources. The information and statistics from official government sources have not been independently verified by us, the [REDACTED], and other [REDACTED], any of our or their respective directors, officers or representatives or any other party, other than CIC, involved in the [REDACTED] and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

You should read the entire document carefully and should not rely on any information contained in press articles or other media regarding us and the [REDACTED].

We strongly caution you not to rely on any information contained in press articles or other media regarding us and the [REDACTED]. Prior to the publication of this document, there has been press and media coverage regarding us. Such press and media coverage may include references to certain information that does not appear in this document, including certain operating and financial information and projections, valuations and other information. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for any such press or media coverage or the accuracy or completeness of any such information or publication. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information or publication. To the extent that any such information is inconsistent or conflicts with the information contained in this document, we disclaim responsibility for it and you should not rely on such information.