An [**REDACTED**] *in our H Shares involves various risks. You should carefully consider all the information in this document and in particular the risks and uncertainties described below before making an* [**REDACTED**] *in our H Shares.*

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

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant net losses since inception. We anticipate that we will continue to incur net losses and may fail to achieve or maintain profitability in the future.

[**REDACTED**] 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 operations primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with our out-license agreements, and proceeds from our Series A Financing. We had not generated any revenue from the sales of commercialized products as of the Latest Practicable Date, and we continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant net losses since our inception. For the year ended December 31, 2021 and the nine months ended September 30, 2021 and 2022, our net losses were RMB889.8 million, RMB658.2 million and RMB321.2 million, respectively.

Substantially all of our net losses during the Track Record Period resulted from costs and expenses incurred by our research and development activities, including those in relation to our preclinical studies and clinical trials, which exceeded the revenue we recognized from out-license agreements and provision of research and development services. For the year ended December 31, 2021 and the nine months ended September 30, 2021 and 2022, our costs and expenses in relation to R&D activities, which represented our cost of sales and research and development expenses, were RMB748.2 million, RMB549.4 million and RMB696.4 million, respectively. See "Financial Information – Description of Selected Components of the Consolidated Statements of Profit or Loss and Other Comprehensive Income" for details. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

We expect to continue to incur net losses in the foreseeable future and that these net losses may increase as we carry out certain activities, including but not limited to the following:

- continue to advance the clinical trials and preclinical studies for our product pipeline;
- seek to discover, develop or in-license additional drug candidates and further expand our product pipeline;
- seek regulatory approvals for our drug candidates to commence commercialization;
- manufacture our drug candidates for clinical trials and for commercial sale;
- develop or manufacture drug candidates under any existing or future license and collaboration arrangements, and the timing and amount of milestone and other payments that we receive from or pay to third parties. See also "– Risks Relating to Dependence on Third Parties – We have entered into license and collaboration agreements with third parties in the development of our drug candidates, and may seek additional license and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected";
- commercialize drug candidates in our pipeline for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- attract and retain skilled personnel; and
- incur additional legal, accounting, investor relations, insurance and other expenses associated with operating as a public company following the completion of this [**REDACTED**].

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

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

During the Track Record Period, we financed our operations, including our R&D activities in relation to our preclinical studies and clinical trials, primarily through borrowings from Kelun Pharmaceutical, payments received in accordance with our license and collaboration agreements, and proceeds from our Series A Financing. As of December 31, 2021 and September 30, 2022, our borrowings from Kelun Pharmaceutical were RMB2,358.0 million and RMB2,761.1 million, respectively. As of the Latest Practicable Date, all the outstanding principal and interest of our borrowings from Kelun Pharmaceutical had been settled. See also "Financial Information – Material Related Party Transactions."

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. Changes in our ability to fund our operations may affect our cash flow and results of operations. Although we are conducting this [**REDACTED**], we may nevertheless require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development of manufacturing capabilities. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- the amount and timing of any milestone and royalty payments we receive from or pay to our current or future collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- the cash requirements of any future acquisitions and/or development of in-licensed pipeline drug candidates; and
- our headcount growth and the associated costs.

As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all.

Our ability to raise funds will also depend on the prevailing financial, economic and market conditions and factors from other aspects, such as our relationship with commercial banks, many of which are beyond our control. See also "– Risks Relating to Our Operations – Disruptions in the financial markets and economic conditions could affect our ability to raise capital." If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities, or the commercialization of one or more of our drug candidates, which may adversely affect our business prospects.

We have a limited operating history as a standalone company, which may make it difficult to predict our future performance.

We are a clinical-stage biopharmaceutical company with a relatively short operating history as a standalone company, starting from 2016 after the completion of the Reorganization. See "History and Corporate Structure." Our operations to date have focused on establishing our intellectual property portfolio, conducting drug discovery, preclinical studies and clinical trials of our drug candidates, forging collaboration and strategic partnerships globally, and organizing and staffing our operations. As of the Latest Practicable Date, we had not yet obtained marketing approval for or commercialized any drug candidates, nor had we generated any revenue from product sales.

We also have limited experience in manufacturing and the sales and marketing of approved drugs. For these reasons, particularly in a rapidly evolving biopharmaceutical industry, it may be difficult to predict our future performance. We may encounter unforeseen expenses, challenges, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business may suffer.

We incurred net liabilities and net current liabilities during the Track Record Period, which may continue into the foreseeable future and expose us to liquidity risk.

As of December 31, 2021 and September 30, 2022, we had net liabilities of RMB2,643.9 million and RMB2,943.9 million, respectively. Our net liabilities position primarily reflected our bank loans and other borrowings, mainly consisting of borrowings from Kelun Pharmaceutical in the amount of RMB2,358.0 million and RMB2,761.1 million, respectively, as of the same date. In addition, we recorded net current liabilities of RMB3,146.6 million and RMB3,503.3 million as of December 31, 2021 and September 30, 2022, respectively, primarily because we invested significant capital into the research and development of our extensive drug pipeline, and building up our technology platforms, manufacturing facilities and other capabilities to complement and support our business. These cash-intensive investments were financed in part through borrowings from Kelun Pharmaceutical and our Series A Financing, which were recorded as current liabilities on our balance sheet. Pursuant to a share subscription and debt-to-equity swap agreement between us, Kelun Pharmaceutical and the other then

Shareholders on January 3, 2023, we settled RMB2.5 billion of the outstanding balance of such borrowings by issuing equity to Kelun Pharmaceutical. As of the Latest Practicable Date, the remaining balance of our borrowings from Kelun Pharmaceutical had been repaid in full by cash. Primarily as a result of this debt-to-equity swap, our net current liabilities decreased to RMB1,264.6 million as of January 31, 2023. See "Financial Information – Material Related Party Transactions" for details.

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. See also "– Risks Relating to Our Financial Position and Need for Additional Capital – 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 may experience net cash outflows from our operating activities from time to time. See also "Financial Information – Liquidity and Capital Resources – Working Capital Sufficiency." 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. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect.

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.

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

We have established Employee Incentive Platforms for the benefit of our core employees, Directors and senior management as remuneration for their services provided to us and to incentivize and reward the eligible persons who have contributed to the success of our Company. For further details, see "History and Corporate Structure – Employee Incentive Platforms." For the year ended December 31, 2021 and the nine months ended September 30, 2021 and 2022, we incurred share-based payment expenses of RMB6.5 million, RMB4.7 million and RMB2.9 million, respectively.

To further incentivize our employees, we may incur additional share-based payment expenses in the future. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a negative effect on our financial performance. Issuance of additional H Shares with respect to such share-based payments may dilute the shareholding of our Shareholders and could result in a decline in the value of our H Shares.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and prospects 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 manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and capital resources in the development of our existing drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future.

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

- favorable safety and efficacy data from our preclinical studies and clinical trials;
- sufficient resources to discover or acquire additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- successful enrollment of patients in, and completion of, clinical trials;
- sufficient supplies of drug products that are either used in combination or in comparison with our drug candidates;
- modifications to the protocols, which may delay the clinical program, regulatory approvals or commercialization, and require us to supplement, modify, or withdraw and refile our applications for regulatory approvals;
- the performance by CROs or other third parties we engage to conduct clinical trials and preclinical studies and their compliance with our protocols and applicable laws without damaging or compromising the integrity of the resulting data;
- the capabilities and competence of our collaborators;
- the success of clinical studies conducted by, or jointly with, our collaborators;
- receipt of regulatory approvals;
- strong commercial manufacturing capabilities;
- successful launch of commercial sales of our drug candidates, if and when approved;

- the obtaining and maintenance of favorable reimbursement from third-party payers for drugs, if and when approved;

- competition with other drug candidates and drugs;

- the obtaining, maintenance and enforcement of patents, trademarks, trade secrets and other intellectual property protections and regulatory exclusivity for our drug candidates;

- successful defense against any claims brought by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party; and

- the continued acceptable safety profile of our drug candidates following regulatory approval.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used modalities. For example, we have built a highly differentiated portfolio of novel ADC drugs – one of the fastest-growing treatment modalities for cancers with vast market potential. Our ADC assets and other drug candidates, given their novelty and differentiated features, may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. Furthermore, a substantial amount of education and training may need to be provided to patients and medical personnel, which potentially increases our sales and marketing expenses. This may have a material adverse effect on future profits generated from our drug candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

As of the Latest Practicable Date, except for A167 for which we had filed an NDA and expected to receive conditional approval in the second half of 2023, all of our other drug candidates were in various phases of preclinical and clinical development. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 in the China market in the second half of 2024 or the first half of 2025. 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, which would have a material adverse effect on our business, financial condition and results of operations.

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

Clinical development is capital-intensive and may demand years of effort to complete, while its outcomes are inherently uncertain and may not be favorable. For instance, despite showing vast potential in clinical trials in the 1980s for cancer treatment, ADCs have presented a major scientific challenge to researchers due to the high degree of technological

sophistication required to design and produce a balanced drug. Only recently have ADCs begun to gain momentum, with a total of 12 FDA-approved ADCs to date. For details, see "Industry Overview – The Antibody-Based Market – The ADC Market."

We may encounter unexpected difficulties while executing our clinical development plans for our drug candidates, including but not limited to the ADC assets. Failure can occur at any time or stage during the clinical development process, which would result in a material and adverse effect on our business, financial condition and results of operations. For instance:

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

- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including negative results or a finding that participants are being exposed to unacceptable health and safety risks;

- we may not be able to reach agreements on acceptable terms with prospective CROs and hospitals as trial centers, the terms of which can be subject to extensive negotiation;

- we may encounter various manufacturing issues, including inability to reach agreements on acceptable terms with CMOs, delay in constructing our new manufacturing facilities, problems with quality control, or ensuring sufficient quantities of our drug candidates for use in a clinical trial;

- subject enrolment may be insufficient or slower than we anticipate, or subjects may drop out at a higher rate than anticipated; and

- our drug candidates may cause adverse events and undesirable side effects, among other unexpected characteristics, which could result in a suspension or termination of an ongoing trial.

Furthermore, the results of preclinical studies and early clinical trials may not be predictive of the success of later-phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily indicate the success of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. It is also common that various aspects of the development programs, such as manufacturing and formulation, are altered along the entire research and development stage in an effort to optimize processes and results, and there can be no assurance that such alterations would help achieve the intended objectives.

There may be significant variability in safety or efficacy results among different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in size and demographics of the enrolled patients (such as genetic differences and patient adherence to the dosage regimen) and the dropout rate among enrolled patients in clinical trials. Differences in the number of clinical trial sites and countries involved may also lead to variability between clinical trials. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and deviate from our expectation, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. See also "– Risks Relating to Government Regulations – The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and uncertain. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our targeted markets, our business may be subject to actual or perceived harm."

We may not be able to identify, discover or in-license new drug candidates, or to identify additional therapeutic opportunities for our drug candidates.

Besides the continued clinical testing, potential approvals and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to identify, discover or in-license additional drug candidates.

There can be no assurance that we will be successful in identifying new drug candidates in the future. For example, although we have developed a proprietary ADC technology platform, which we believe enables us to design, evaluate and select candidates and continue to enrich our pipeline, we cannot guarantee that we will successfully identify potential drug candidates as expected. Some drug candidates may be technically challenging to develop and manufacture. Drug candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. We have also pursued, and may continue to pursue, collaboration with third parties in the discovery and development of potential drug candidates, including through co-development and licensing arrangements. For details, see "Business – Our License and Collaboration Arrangements." However, there can be no assurance that such license and collaboration will deliver the expected results.

Research programs to identify new drug candidates and to develop our drug candidates for additional indications require substantial technical, financial and human resources. We may invest efforts and resources in potential drug candidates or indication expansions that ultimately prove to be unsuccessful. Any of the foregoing events will have a material adverse effect on our business, results of operations and prospects.

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

As we have limited financial and managerial resources, we focus our product pipeline on research programs and drug candidates that we identify for selected indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for selected indications may not yield any commercially viable products. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through licensing, collaboration or royalty arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. We may experience difficulties in subject enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the subject eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of subjects to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain subject consents;

- the risk that subjects enrolled in clinical trials will not complete a clinical trial; and

- the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials may compete with our competitors' clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates. Such competition will likely reduce the number and types of subjects available to us, as some patients might opt to enroll in a trial being conducted by our competitors instead of ours. 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 delay or prevent the completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Adverse events or undesirable side effects caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Adverse events ("AEs") and undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a narrowed scope of indications or a more restrictive label of our drug candidates, 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. Results of trials conducted by us or by our licensing partners with respect to our licensed drug candidates could reveal a high and unacceptable severity or prevalence of certain AEs. In such an event, such trials could be suspended or terminated and the NMPA, the FDA, or other comparable regulatory authorities could order us or our licensing partners, as applicable, to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. AEs related to our drug candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

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, but are not limited to, the following:

- regulatory authorities may withdraw their approvals of or revoke the licenses for the drug candidate;

- we, or our licensing partners, may have to suspend marketing of the drug candidate;

- regulatory authorities may require additional warnings on the label;

- the NMPA, the FDA or a comparable regulatory authority may require the establishment of a Risk Evaluation and Mitigation Strategy (REMS), or other similar plans, which may restrict distribution of our drugs and impose burdensome implementation requirements on us, among other risk mitigation tools;

- we, or our licensing partners, may be required to change the way the drug candidate is administered, or conduct specific post-marketing studies;

- we could be subject to litigation proceedings and held liable for harm caused to subjects or patients; and

- our reputation may suffer.

Further, combination therapy using our drug candidates together with third-party agents may involve AEs, which in some cases 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.

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, such as SKB264 and A167, for combination therapies. For example, we obtained IND approvals from the NMPA in March and April 2022 for two phase 2 clinical trials for SKB264 combination therapies – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as an early-line treatment for advanced EGFR-wild type and EGFR-mutant NSCLC and a phase 2 trial of SKB264 with or without A167 as a 1L treatment for advanced TNBC, for which we expect to complete patient enrollment in the second half of 2023 and the first half of 2024, respectively. We also received IND approvals from the NMPA and FDA in July 2022 and November 2022, respectively, for a global phase 2 basket study of SKB264 in combination with Keytruda for selected solid tumors, which we commenced in December 2022 in both China and the U.S. For SKB264's phase 2 basket study as combination therapies (including with Keytruda, osimertinib and chemotherapy) for advanced EGFR-wild type and EGFR-mutant NSCLC, we received IND approval from the NMPA in January 2023.

If the NMPA, the FDA or other comparable regulatory authorities revokes its approvals of the pharmaceutical products or medical treatments we intend to use in combination with our drug candidates, we may not be able to develop or market our drug candidates as a combination therapy as planned. In addition, if safety or efficacy issues arise with these pharmaceutical products or medical treatments that we seek to combine with our drug candidates, we may also experience significant regulatory delays, and be required to re-design or terminate the relevant

clinical trials. Moreover, if manufacturing or other issues result in a supply shortage of any component in the combination therapies we are developing, we may not be able to complete clinical development of our drug candidates under our target timetable 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 example, we have made significant efforts to develop our core proprietary technology platforms, namely, our ADC platform, biologics platforms and small molecule platform, which allow us to continuously develop and manufacture a robust pipeline of drug candidates. For the year ended December 31, 2021 and the nine months ended September 30, 2021 and 2022, our costs and expenses in relation to R&D activities, which represented our cost of sales and research and development expenses, were RMB748.2 million, RMB549.4 million and RMB696.4 million, respectively. We intend to continue to strengthen our technical capabilities in the development and manufacture of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner. 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.

We may 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 highly competitive and rapidly changing. While we focus on developing drug candidates with the potential to become novel or highly differentiated drugs, we face competition with respect to our current drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future.

Large multinational pharmaceutical companies, well-established biopharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of indications which our drug candidates also target. For example, in recent years, an increasing number of biotechnology companies have joined the competition in the research and development of ADCs, with large pharmaceutical companies leading the

competition and small biotechnology companies making frequent breakthroughs. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or Pipeline similar to our approach, and others are based on different approaches. See "Business – Our Pipeline."

Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Many of our competitors have substantially greater financial, technical and other resources, such as more advanced commercial infrastructure, more drug candidates in late-stage clinical development, more seasoned research and development staff and well-established marketing and manufacturing teams than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in our competitors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better acceptance in the markets in which we operate or have established a competitive position.

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

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We have entered into license and collaboration agreements with third parties in the development of our drug candidates, and may seek additional license and collaboration opportunities in the future, and we may not realize the benefits of such partnerships as expected.

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our drug development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. To date, we have entered into nine out-license agreements, including three license and collaboration agreements with MSD to develop up to nine ADC assets for cancer treatment. See "Business – Our License and Collaboration Arrangements" for details.

Our revenue from license and collaboration agreements increased significantly during the Track Record Period and our results of operations have been, and may continue to be, affected by such arrangements. For the year ended December 31, 2021 and the nine months ended September 30, 2021 and 2022, 13.9%, 17.1% and 98.1%, respectively, of our total revenue was derived from our license and collaboration agreements with MSD and other licensing partners. We also generated revenue from provision of research and development services to Kelun Group and other third parties, which constituted 86.1%, 82.9% and 1.9%, respectively, of our total revenue for the same periods. License and collaboration agreements involving our drug candidates are subject to various risks, which may include the followings:

- the license and collaboration agreements may be terminated upon a short notice, or if we or our business partners fail to comply with the obligations as set out in the respective agreements. Our business partners may elect to cease collaboration due to change in their strategic focus, potential acquisition of competitive drugs, availability of funding, or other external factors. Termination of license and collaboration arrangements may result in a need for additional capital to pursue further development or commercialization of the relevant drug candidates;

- the milestone payments and royalties under the license agreements are conditioned upon the achievements of certain regulatory, development and commercialization targets. We cannot guarantee that we will be able to receive the aggregate amount as set out in the relevant license and collaboration agreements;

- our business partners may have significant discretion in determining the efforts and resources that they will apply under license and collaboration agreements;

- our business partners could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;

- our business partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- our business partners may own or co-own intellectual property covering our drug candidates or future drugs that arise from our license and collaboration agreements with them, in such cases we may not have exclusive right over such intellectual property; and

- disputes may arise between us and our business partners that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources. See also "– Risks Relating to Our Intellectual Property Rights – Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by others."

For these and other reasons, we may not achieve the outcomes and synergies expected from our license and collaboration arrangements. These license and collaboration arrangements are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. We may face operational and financial risks including increase in near- and long-term expenditures, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention. Even if we achieve the expected benefits, we may not be able to do so within the anticipated time frame.

We face significant competition in seeking appropriate strategic partners and the negotiation process can be time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may be required to relinquish some or all of the control over the future success of that drug candidate to the third party. The collaborators may also consider alternative drug candidates or technologies that may be available. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits. See also "– Risks Relating to Our Operations – Our potential engagement in acquisitions or strategic partnerships in the future may increase our capital requirements, cause dilution for our Shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks."

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into license and collaboration arrangements or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

As a result, we cannot be certain that, following a license and collaboration arrangement, we will achieve the revenue or net income that justifies such transaction or such other benefits that caused us to enter into the arrangement. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of our drug candidates and certain of these third parties from which we have been granted licenses themselves rely on licenses from other third parties. For example, under the co-development agreement among our Company, Kelun Research Institute, Levena Contortis, and Sorrento Therapeutics, Inc. (NYSE: SRNE) for A166, our anti-HER2 ADC, we were granted the right to utilize Levena's all patents (registered or pending) and other technical know-how related to its linker and payloads. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our future approved drugs. As a result, we may not be able to develop, export or sell our drug products outside of the fields or territories as stipulated by the license and collaboration agreements or prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensing partners fail to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject to such licensed rights could be adversely affected. Our licensing partners may have relied on third-party consultants or collaborators or on funds from third parties, or on upstream licenses from third parties, such that our licensing partners are not the sole and exclusive owners of the intellectual property rights we in-license. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Such license agreements set out various procedures and timelines with respect to, among other matters, clinical development, commercialization, and financial obligations such as milestone payments and royalties. The terms of these agreements are complex and can be subject to multiple interpretations. The resolution of any disagreements arising from these agreements could, for example, eliminate or narrow what we believe to be the scope of our rights to the relevant intellectual properties or technologies, or increase what we believe to be our financial or other obligations under the relevant agreements. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate such agreements, in which event we might lose the ability to develop, manufacture or market certain drugs, or face claims for monetary damages or other penalties under the respective agreements. 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.

Moreover, if any of our licensing partners encounter financial problems or changes in business focus, some or all of our rights under the license agreements may be terminated. For details, see "Business – Our License and Collaboration Arrangements." As such, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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 upon and plan to continue to rely upon third-party CROs, clinical trial sites, consultants and other third parties to monitor, support and conduct preclinical studies and clinical trials of our drug candidates. As a result, we do not have full control over their activities or the quality, timing and cost of these studies. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities.

In particular, we, our CROs and our clinical investigators are required to comply with GCP, GLP and other regulatory regulations and guidelines enforced by the NMPA, the FDA, and comparable regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities may enforce these GCP, GLP or other regulatory requirements through periodic inspections of trial sponsors, investigators and trial sites. In addition, our clinical trials must be conducted with drug candidates or products produced under current cGMP requirements.

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 we or 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. Failure to comply with these regulations may lead us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Similarly, if other third parties fail to meet expected deadlines, timely transfer to us any requisite information, adhere to protocols or act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a sub-standard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, the clinical trials of our drug candidates may be compromised, delayed, prolonged, suspended or terminated, or our data may be rejected by the NMPA, the FDA, or other comparable regulatory

authorities. In addition, the use of these third parties may require us to disclose our proprietary information or confidential information concerning the subjects enrolled in our clinical trials from time to time, which could increase the risk that such information will be misappropriated. Though we carefully manage our relationships with our CROs and other third-party service providers, there can be no assurance that we will not encounter challenges in the future or that these challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, we may not be able to enter into arrangements with alternative CROs and other third parties in a timely manner or do so on commercially reasonable terms, if our existing relationships with these third parties terminate. Switching or adding CROs and other third parties involves additional cost and delays, which can materially affect our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.

We depend on third parties to provide a stable and adequate supply of quality materials and products for our drug development and manufacturing 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 the manufacturing of drugs for clinical trials. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our drug candidates.

Any disruption in production or the inability of our suppliers to provide adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates. Moreover, we expect our demand for such raw materials and products to increase as we expand our business scale and commercialize our drug candidates, but there is no assurance that current suppliers have the capacity to meet our demand. We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In addition, although we have implemented quality inspection on such raw materials and products before using them in the manufacturing process, we cannot assure you that we will be able to identify and rectify all quality issues.

We cannot assure you that these third-party suppliers will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the raw materials and products supplied to us, and cause delays in clinical trials and regulatory filings or even recall of our products. The non-compliance of these third parties may also subject us to potential product liability claims, result in our failure to comply with the continuing regulatory requirements, and cause us to incur significant costs, which may have a material and adverse effect on our business, financial condition and results of operations.

We may 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.

During the Track Record Period, we outsourced certain manufacturing activities to reputable CMOs in China. See "Business – Manufacturing – CMOs" for details. Going forward, we intend to continue to engage third-party CMOs to manufacture our drug candidates for our research and development activities and commercial sales. Reliance on third-party CMOs exposes us to certain risks, including but not limited to the following:

- we may be unable to identify CMOs on acceptable terms or at all because the number of qualified CMOs is limited and the NMPA, the FDA or other comparable regulatory authorities must evaluate and/or approve any CMOs as part of their regulatory oversight of our drug candidates;

- our CMOs may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs;

- our CMOs are subject to periodic inspections and other government regulations by the NMPA, the FDA or other comparable regulatory authorities, including to ensure strict compliance with the cGMP. We do not have full control over our CMOs' compliance with these regulations and requirements;

- our CMOs might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;

- our CMOs may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed;

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

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

- our CMOs could terminate their agreements with us;

- raw materials and products procured by certain CMOs may not be readily obtainable elsewhere; and

- natural or man-made disasters, labor disputes, unstable political environments and other events beyond our control may lead to interruption of the manufacturing process.

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

We may fail to effectively manage our network of distributors after our drug candidates are successfully launched. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.

We may rely in part on third-party distributors to distribute our drug candidates upon their commercialization. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely and effective delivery of our products to the relevant markets. We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach the distribution agreements and the policies and measures we have in place to manage their distribution. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected:

- breaching the distribution agreements or our policies and measures;

- failing to maintain the requisite licenses, permits or approvals, or failure to comply with applicable regulatory requirements when selling our products; or

- violating anti-corruption, anti-bribery, competition or other laws and regulations of China or other jurisdictions.

Any violation or alleged violation by our distributors of the distribution agreements, our policies or any applicable laws and regulations could expose us to liabilities and monetary damages, a decrease in the market value of our brand and an unfavorable public perception about the quality of our products, resulting in a material adverse effect on our business, financial condition, results of operations and prospects.

Our relationships with certain principal investigators, KOLs and leading hospitals may affect the clinical development and future marketing of our products.

Our relationships with principal investigators, KOLs, and leading hospitals play an important role in our R&D and marketing activities. We implement a clinical demand-oriented and highly responsive R&D strategy by establishing extensive interaction channels with principal investigators, KOLs, leading hospitals to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drugs and improve our existing drug candidates. We are planning to develop our own commercialization team and network, with an initial focus on Class III hospitals and

leading physicians across China's extensive local markets. We are also committed to enhancing our collaborations with KOLs, top hospitals and academic institutions, in China and globally, to ensure our timely access to cutting-edge research and support our existing and future pipeline. See also "Business – Our Development Strategies" and "Business – Commercialization."

However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, KOLs and leading hospitals, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our R&D process, may be inaccurate and lead us to develop drugs that do not have significant market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable drugs. If we are unable to develop new drugs or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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 (i) 63 issued patents in China, (ii) 20 issued patents in the U.S., (iii) 46 issued patents in other jurisdictions, and (iv) 253 pending patent applications, including 108 in China, 15 in the U.S., 17 under the Patent Cooperation Treaty (PCT) and 114 in other jurisdictions. See "Business – Intellectual Property" for details. This process is expensive and time-consuming, and we or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

The patent position of biopharmaceutical companies generally involves complex legal and factual questions, and can be frequently litigated. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not be granted with approvals that effectively prevent third parties from commercializing competitive technologies and drug candidates. The patent examination process may require us or our business partners to narrow the scope of our or our business partners' pending and future patent applications, which may then limit the scope of patent protection that could be obtained. There can be no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent. Moreover, if there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable.

Even if patents are issued on these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. We or our business partners may become involved in interference, *inter partes* review, post-grant review, *ex parte* reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

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. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours. 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 due to non-compliance.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (the "CNIPA"), the United States Patent and Trademark Office (the "USPTO") and other applicable patent agencies in several stages over the lifetime of a patent. The CNIPA, the USPTO and other applicable patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

If our patent terms expire before or soon after our drug candidates are approved, 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.

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Even if patents covering our drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications. Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible

for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it, may be extended. Similarly, the October 2020 Amendment to the PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension of up to a maximum length of five years. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements.

Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed.

In addition, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. Besides this, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property rights, or prevent unfair competition by third parties, throughout the world.

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into certain jurisdictions. Competitors may

use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to certain jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in certain other countries. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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

We own a number of trademarks in China, the U.S. and other jurisdictions. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

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

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

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

Furthermore, many of our employees, consultants and advisors were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and advisors, including our senior management members, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors are under no non-competition obligations to their former employers at the time of hiring, and that they do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management or general management, but there is no assurance that we will not be subject to such claims or involved in litigations to defend against such claims in the future. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Further, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel and could 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 and impair the intellectual property protection of our drug candidates.

Changes in intellectual property laws or their interpretation in China, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the scope and value of our intellectual property rights.

For example, after March 2013, under the Leahy-Smith America Invents Act ("Leahy-Smith Act"), the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

There could be similar changes in the laws of China, such as the October 2020 Amendment to the PRC Patent Law. See "– Risks Relating to Our Intellectual Property Rights – 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." Such changes in laws either of China or foreign jurisdictions may impact the value of our patent rights or our other intellectual property rights, all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial conditions, results of operations and prospects.

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.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights (including those transferred or licensed from our Controlling Shareholder or other third parties) could be challenged or invalidated. For example, although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. On the other hand, competitors or other third parties may infringe or misappropriate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages. In addition, if the breadth or strength of protection provided by our patents and other intellectual property rights is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of intellectual property protection could have a material adverse impact on one or more of our drug candidates and our business.

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. Even if successful, litigation may result in substantial costs and distraction of our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If the public, securities analysts or [**REDACTED**] perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the [**REDACTED**] of our Shares. There is no assurance that our drug candidates will not be subject to the same risks.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantages.

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 advantages. The following examples are illustrative:

- others may be able to make drug candidates that are the same as or similar to our drug candidates but that are not covered by the claims of the patents that we own or may have exclusively licensed;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

- third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and

- we may not develop additional technologies that are patentable.

RISKS RELATING TO GOVERNMENT REGULATIONS

All material aspects of the research, development, manufacturing and commercialization of biopharmaceutical products are heavily regulated. Any failure to comply with relevant laws, regulations and industry standards or any adverse actions by the regulatory authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.

All jurisdictions in which we intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. See also "– Risks Relating to Doing Business in China." Apart from our focus on the China market, we are actively seeking opportunities to expand our global footprint and raise international brand awareness. For more details, please see "Business – Our Development Strategies." Such jurisdictions all strictly regulate the biopharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and capital resources. Failure to comply with the applicable regulatory requirements in the jurisdictions we operate or target to operate in the future at any time during the drug development process or

approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include but are not limited to a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our reputation and our business, financial condition, results of operations and prospects.

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. For example, we may need to obtain clearance from the NMPA, the FDA or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, and file an NDA, BLA or other similar applications to seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, 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 uncertain. 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.

The time required to obtain approvals from the NMPA, the FDA, and other comparable regulatory authorities is unpredictable and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take many years to obtain, following the commencement of preclinical studies and clinical trials. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our drug candidates will be approved for sale in those 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.

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

- disagreement in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- insufficient or suboptimal data collected from the clinical trials, or failure of our clinical trial results to meet the level of statistical and medical significance required for approvals;
- failure of our clinical trial process to pass GCP inspections;
- unexpected changes in regulations, testing requirements, or approval policies that render our preclinical and clinical data insufficient for approval;
- failure of our clinical sites to pass audits carried out by the NMPA, the FDA or other comparable regulatory authorities, resulting in a potential invalidation of our research data; and
- findings of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies, such as failure to pass cGMP inspections.

The NMPA, the FDA or other comparable regulatory authorities may require more information to support approval, including additional preclinical or clinical data, which may result in delay in regulatory approval and commercialization plans or denial of regulatory approval. In the case where an approval is issued, regulatory authorities may approve fewer indications, including undesired indications, of our drug candidates than the indications we applied for, or grant approvals contingent on the performance of post-marketing clinical trials. Failure to obtain regulatory approvals in a timely manner, or at all, or failure to obtain regulatory approvals with an intended scope of indications could have a negative impact on the commercial prospects of our drug candidates, and may cause reputational damage. If any of our drug candidates fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities or does not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such drug candidate despite the significant amount of resources we would have spent on its development, which could materially adversely affect our business, financial condition, results of operations and prospects.

If we are unable to obtain approval from the NMPA, the FDA and other comparable regulatory authorities for our drug candidates to be eligible for an expedited registration pathway as innovative or breakthrough therapy, the time and cost we incur to obtain regulatory approvals may increase.

The NMPA, the FDA and the comparable regulatory authorities in other jurisdictions may have implemented expedited review programs for drug candidates, among others, which are innovative drug applications, or which treat a serious or life-threatening condition and provide meaningful therapeutic benefit over available therapies. The NMPA's Breakthrough Therapy Designation, for example, is intended to facilitate and expedite the development and review of an investigational drug to treat a serious disease or condition when preliminary clinical evidence indicates that the drug has demonstrated substantial improvement over current therapies. Similarly, the FDA may facilitate the development and expedite the review of pharmaceutical products that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical need for the condition.

Supported by its promising proof-of-concept results, SKB264, our TROP2 ADC, was granted Breakthrough Therapy Designation by the NMPA for advanced TNBC in July 2022 and for EGFR-TKI failed EGFR-mutant advanced NSCLC in January 2023. There can be no assurance, however, that the regulatory authorities will consider granting Breakthrough Therapy Designation or other expedited review programs for our other or future drug candidates, or that we will decide to pursue or submit any applications for accelerated approvals or any other form of expedited development, review or approvals. Similarly, there can be no assurance that, after receiving feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approvals or any other form of expedited development, review or approvals, even if we initially decide to do so. Furthermore, there can be no assurance that such a submission or application will be accepted for filing, or that any expedited development, review or approvals will be granted on a timely basis, or at all. Any failure to obtain accelerated approvals or any other form of expedited development, review or approvals for our drug candidates could result in a longer period of time prior to the commercialization of such drug candidate, an increase in the development expenses for such drug candidate and an adverse impact on our competitive position in the market.

Our future approved drug candidates will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expense. We may face penalties and other negative consequences if we fail to comply with these regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA, the FDA or other comparable regulatory authorities approve any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event 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 chemistry, manufacturing, and controls ("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 the conditions of approval, or contain requirements for potentially costly post-marketing studies, including, if applicable, phase 4 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, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

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

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business, financial condition and prospects.

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, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. See also "– Risks Relating to Manufacturing and Commercialization of Our Drug Candidates – Our drug candidates may not be covered by insurance or reimbursement programs or may become subject to unfavorable insurance policies or reimbursement practices, either of which could harm our business, and we may be subject to unfavorable pricing regulations, which could make it difficult for us to sell our drugs profitably."

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. In December 2020, for instance, the National Health Commission ("NHC") released the Notice on the Temporary Measures Regulating the Clinical Use of Oncology Drugs (《關於印發抗腫瘤藥物臨床應用管理辦法(試行)的通知》), followed by more detailed guidance announced in its Measurement Criteria for the Reasonable Clinical Use of Oncology Drugs (2021 Version) (《抗腫瘤藥物臨床合理應用管理指標》(2021年版)) in June 2021 ("Oncology Drug Guidance"), according to which several factors will be considered to evaluate whether the oncology drugs, especially "restricted class drugs," are under reasonable use by the medical institutions, in terms of usage rate and amount, among other criteria. The Oncology Drug Guidance sets out to designate anti-tumor drugs as "restricted class drugs" if they, among other characteristics, exhibit a poor safety profile, require sophisticated clinical administration, new to the market or prohibitively priced. If our oncology drug candidates are categorized as "restricted class drugs" after commercialization, we may face a decreased demand from the medical institutions and patients, which may adversely affect the commercialization and marketing of such drug candidates. 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 has been commercialized to 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 uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these laws and regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

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 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 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 including, for example, substantial operational costs associated with changes to our data processing practices. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, and results of operations or prospects.

In recent years, the PRC government has promulgated an increasing number of laws and regulations governing the various aspects of information security, data collection and privacy protection, including, among others, the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), the Provisions on Protection of Personal Information of Telecommunication and Internet Users (《電信和互聯網用戶個人信息保護規定》), the Cybersecurity Review Measures (《網絡安全審查辦法》), the Data Security Law of the PRC (《中華人民共和國數據安全法》) which became effective from September 1, 2021, and the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》) which became effective from November 1, 2021. Under the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), prior consent shall be obtained from the individual when personal information is being processed, unless explicitly permitted under certain circumstances. Furthermore, any data processing activities in relation to sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old are not allowed unless such activities have a specific purpose, are highly necessary and strict protective measures have been taken. Certain industry-specific laws and regulations may also affect the collection and transfer of personal data in China, including Administrative Regulations on Human Genetic Resources of the People's Republic of China (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our clinical trial practices, potentially resulting in the confiscation of human genetic resources samples and associated data and administrative fines.

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they could be held liable for the damage caused. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects' medical records. However, these measures may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence.

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

Any change in the applicable laws and regulations could affect our ability to use medical data and subject us to liability for the improper use of such data. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

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

We are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our facilities can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the relevant facilities in certain jurisdictions.

We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our facilities may affect our abilities to develop, manufacture and commercialize our pipeline products as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, and health and safety laws and regulations, we may be subject to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions in our business operations. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial condition, results of operations and prospects.

In addition, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of research, testing, development and manufacturing of biopharmaceutical products. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could materially and adversely our business. Other adverse effects could result from such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facilities temporarily, or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects.

Although we maintain insurance policies that cover losses arising from accidents and natural calamities in respect of our machinery, equipment, inventory and other fixed assets in our research and manufacturing facilities, as well as environmental pollution liability insurance and public liability insurance, these insurance policies may not provide adequate coverage against potential liabilities resulting from the use of or exposure to hazardous materials. Furthermore, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

We 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 and other jurisdictions, which could 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 NMPA's 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, including the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》), PRC Criminal Law (《中華人民共和國刑法》); doctor payment transparency laws and regulations which primarily include the Affordable Care Act (《平價醫療法案》) and the Physician Payments Sunshine Act (《醫師酬勞陽光法案》). These laws may impact, among others, our proposed sales, marketing and education programs.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focusing on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational damage, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a material adverse effect on our business and results of operations.

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. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. See also "– Risks Relating to Our Operations – We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties."

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, and if we fail to comply with such requirements, we

could be subject to penalties and other negative consequences. 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.

RISKS RELATING TO 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 and others in the medical community.

Even if our drug candidates receive the requisite regulatory approval, they may fail to gain sufficient market acceptance by physicians, patients, third-party payers and other relevant parties in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs and we may not become profitable. The degree of market acceptance of our drug candidates will depend on a number of factors, including but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians' and patients' perception of our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the NMPA, the FDA or other applicable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, the FDA or other applicable regulatory authorities;
- the timing of market introduction of our drug candidates as well as competing drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drug candidates;
- the availability of adequate coverage and reimbursement by government authorities;

- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;

- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and

- the effectiveness of our sales and marketing efforts.

Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

We have limited experience in commercializing innovative drugs. 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, primarily undertaking preclinical studies and conducting clinical trials. Although members of our management have years of experience relating to marketing and commercialization, we have not yet demonstrated an ability to launch and commercialize any of our drug candidates. We only recently started the process of building a commercial team and a sales force for our drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing drug candidates.

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

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

Our drug candidates may not be covered by insurance or reimbursement programs or may become subject to unfavorable insurance policies or reimbursement practices, either of which could harm our business, and we may be subject to unfavorable pricing regulations, which could make it difficult for us to sell our drugs profitably.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. We intend to seek approval to market our drug candidates in China, the U.S. and in other jurisdictions. In China, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. 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.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 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 China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or 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 commercial sales 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 that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drug candidates. 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.

We cannot be sure that reimbursement will be available for any approved drug candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidates that we commercialize. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

There may also be significant delays in obtaining reimbursement for approved drug candidates, and reimbursement coverage may be more limited than the approved indications of the drug candidates by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the uses of the drugs and the clinical setting in which the drugs are used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Our inability to promptly obtain reimbursement coverage at intended payment rates for our drug candidates and any new drug candidates that we develop could have a material adverse effect on our business, operating results, and overall financial conditions.

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 markets for our current or future drug candidates may be smaller than our estimates.

Our projections of the number of patients who have the potential to benefit from treatment with our drug 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. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our drug candidates may be smaller than our estimates.

Furthermore, there is no guarantee that any of our drug candidates, even if approved, would be approved for the line of therapy we are aiming for. For example, cancer therapies may be characterized as first line, second line or later line therapy depending on options for treatment and prior treatments received. For indications with well-established standard of care therapies, the NMPA, the FDA and other comparable regulatory authorities may approve new therapies initially only for later lines of therapy. While we may seek approval for our drug candidates as an early-line therapy for certain indications, there is no guarantee that they will be approved as such. As a result, even if we obtain market approval for our drug candidates, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

The manufacturing of biopharmaceutical products is a complex process which requires significant expertise and capital investment, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.

As of the Latest Practicable Date, we had not commercialized any drug candidates and our drug manufacturing activities are primarily to facilitate our preclinical studies and clinical trials. As a result, we have limited experience in manufacturing biopharmaceutical products on a commercial scale, which is a complex process requiring significant expertise and capital investment, in part due to strict regulatory requirements.

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) delays in the construction of new manufacturing facilities or expansion of any future manufacturing facilities, (v) changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, (vi) changes in the type of products produced, (vii) advances in manufacturing techniques, (viii) physical limitations that could inhibit continuous supply, and (ix) 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. If problems are not discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

We face additional manufacturing risks in relation to the CMOs we engage from time to time. See "– Risks Relating to Dependence on Third Parties – We may 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 cannot assure you that issues relating to the manufacturing of our drug candidates will not occur in the future, either relating to our own manufacturing facilities or the third-party CMOs we engage.

Failure to obtain and maintain regulatory approvals for our manufacturing facilities, delays in the construction of our new manufacturing facilities, and any disruption or suspension of manufacturing activities may affect our business and results of operations.

To date, our manufacturing activities are primarily limited to supporting our drug development process. Anticipating future commercialization, we are building up our own cGMP-compliant pilot-scale and manufacturing capabilities to ensure delivery of high-quality drug products. We also engaged, and will continue to engage, industry-recognized CMOs to supplement our in-house capacity so as to enhance efficiency and reduce operational and regulatory compliance costs. For more details, see "Business – Manufacturing." If we fail to obtain and maintain regulatory approvals for our manufacturing facilities, or encounter delays in the construction or the approval of our new manufacturing facilities, we may not be able to

manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could also require us to raise additional funds from other sources.

Our manufacturing facilities are required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, the FDA or other comparable regulatory authorities to ensure compliance with cGMP regulations. Our manufacturing facilities are designed in compliance with the NMPA and FDA's regulatory requirements and cGMP standards in China, the U.S. and Europe. We cannot guarantee, however, that we will be able to adequately follow and document our adherence to such cGMP regulations or other regulatory requirements. Remediating deficiencies, if any, can be laborious, time consuming and costly. Failure to obtain and maintain such regulatory approvals may materially affect our R&D activities, and seriously delay the clinical trials and commercialization of our drug candidates.

We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA, the FDA or other comparable regulatory authority standards or specifications, maintain consistent and acceptable production costs, experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment in them. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities. We may also be subject to sanctions for failure to comply with applicable regulations, including fines, injunctions, penalties, suspension of clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, suspension or withdrawal of approvals, supply disruptions, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which may harm our business.

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

The quality of our products, including drug candidates manufactured by us for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. We operate a comprehensive quality control system which extends across all key stages of the R&D, manufacturing and commercialization processes. This system is established and refined in accordance with the rigorous regulations and guidelines in China, the U.S. and Europe. See "Business – Quality Control." However, 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 deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, jeopardize any cGMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

Counterfeit biopharmaceutical products and the illegal and/or parallel import of competing drugs may reduce demand for our drug candidates, which could have a negative impact on our reputation and business.

The illegal import of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we plan to commercialize our products. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our drugs and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Furthermore, certain products distributed or sold in the biopharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their usage or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The regulatory control and law enforcement system in relation to the counterfeit pharmaceutical products, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our drug candidates. In addition, theft of inventory at warehouses, plants or while in-transit, which is not properly stored and which is sold through unauthorized channels. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences, which potentially exposes us to product liability claims, government investigations, and other disputes and negative consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators' brand name(s).

RISKS RELATING TO OUR OPERATIONS

Our future success depends in part on our ability to retain our senior management, scientific employees and other qualified personnel.

We are highly dependent on the expertise and insights of our senior management team. Recruiting and retaining qualified scientific, technical, clinical, manufacturing, and sales and marketing personnel in the future will also be critical to our success. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Furthermore, replacing executive officers, scientific employees, and other qualified personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous biopharmaceutical companies for similar personnel. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

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

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." As we continue to implement our development strategies, we intend to expand our operations and add a significant number of managerial, R&D, manufacturing, sales and marketing, and other personnel. Our recent growth and any future growth will also impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;

- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties;

- improving our operational, financial and management controls, reporting systems and procedures in line with our growth.

If we are not able to effectively manage our growth and further expand our organization, we may not be able to successfully develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our potential engagement in acquisitions or strategic partnerships in the future may increase our capital requirements, cause dilution for our Shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network, among others.

Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including but not limited to:

- substantial time and expenses incurred during negotiation, which do not guarantee the successful consummation of an acquisition or strategic partnership;
- impact on our financial results, such as occurrence of goodwill impairment charges and amortization expenses for intangible assets;
- increased operating expenses, including research and development expenses due to an increased number of drug candidates, administrative expenses as well as selling and distribution expenses, which result in an increased cash requirements;
- the assumption of additional indebtedness or contingents;
- the issuance of our equity securities resulting in dilution to our Shareholders;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, or failure to otherwise achieve intended synergies in the combined operations;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and drug candidates and regulatory approvals;

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and/or

- deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in the acquired business we discover after such acquisition, which may subject us to penalties, lawsuits or other liabilities.

Further, any difficulties in the integration of acquired businesses, product or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our reputation, business, financial condition and results of operations. 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.

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

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and intellectual property rights. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, claims, disputes or legal proceedings against us may be due to actions taken by our counterparties, such as our suppliers, CROs and other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

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

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. However, our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as CMOs, CSOs and KOLs, to advance our clinical development programs, expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties.

Any disputes, legal proceedings, regulatory inquiries, investigations or other actions involving us, our Controlling Shareholder, management, employees, business partners and affiliates, or any perceived unethical, fraudulent, or inappropriate conduct by any of the above, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such disputes, legal proceedings, regulatory inquiries, investigations or other actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

We may be exposed to the risks of conducting business globally.

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 seeking licensing and co-development opportunities with global multinational companies, 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 but not limited to:

- efforts to enter into license and collaboration arrangements with third parties may increase our expenses or divert our management's attention from the development of drug candidates;

- political and economic instability as well as geopolitical tensions, including the threat of war or terrorist attacks (notably the Russia-Ukraine conflicts and the reaction of the international community, the consequences of which on the financial markets and the global business climate remain uncertain);

- differing regulatory requirements for drug approvals and marketing internationally;

- potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;

- difficulty of effective enforcement of contractual provisions in local jurisdictions;

- potentially reduced protection for intellectual property rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements, and delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions;

- significant adverse changes in currency exchange rates;

- compliance with tax, employment, immigration and labor laws for employees traveling abroad; and

- business interruptions resulting from geo-political actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue and profits from international markets.

We benefit from certain preferential tax treatments and government grants, the expiration of or changes to which could adversely affect our profitability.

We currently benefit from certain preferential tax treatments. According to the EIT Law and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. We obtained our certificate of High and New Technology Enterprise on December 3, 2020 and is entitled to preferential income tax of 15% for the years from 2020 to 2022. We cannot assure you that these preferential tax treatments will continue to be available to us in the future, or that these preferential tax treatments will not be changed, as a result of changes in government policy, administrative decisions or otherwise, in which case our financial condition and results of operations may be adversely affected. See Note 7 to the Accountants' Report in Appendix I to this document for details.

Moreover, we recorded government grants of RMB16.7 million, RMB10.2 million and RMB4.8 million for the year ended December 31, 2021 and the nine months ended September 30, 2021 and 2022, respectively. These government grants primarily represent government subsidies from state and local government authorities for the purpose of compensating us for the expenses in relation to our R&D activities and construction of our manufacturing facilities. These government grants are provided to us at the discretion of the relevant government authorities, who could determine at any time to eliminate or reduce these financial incentives, and may therefore vary from period to period going forward. For more details, please see "Financial Information – Description of Selected Components of the Consolidated Statements of Profit or Loss And Other Comprehensive Income – Other Net Income/(Expense)."

Since our receipt of the government grants and eligibility for the preferential income tax treatment are subject to the government's discretion and approval process, our net income in a particular period may be higher or lower relative to other periods partly due to the potential changes in the government grants we actually receive or preferential income tax treatment we enjoy, in addition to any business or operational factors that we may otherwise experience. There is no assurance that we will continue to receive such government grants at a similar level or at all, or be eligible to enjoy the preferential income tax treatment in the future. The discontinuation of preferential tax treatments, government grants and other financial incentives currently available to us could have an adverse effect on our financial condition, results of operations, cash flows and prospects.

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. In recent years, the average labor cost in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been steadily increasing as the competition for qualified employees has become more intense. We cannot assure you that there will be no further 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. See also "– Risks Relating to Our Financial Position and Need for Additional Capital – Share-based payments may have a material and adverse effect on our financial performance and cause shareholding dilution to our Shareholders."

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. Such plan consists of pension insurance, medical insurance, work-related injury insurance, maternity insurance, unemployment insurance and housing provident fund. The amount we are required to contribute for each of our employees under such plan should be calculated based on the actual income of our employees, together with the minimum and maximum level as from time to time prescribed by national laws and regulations and local authorities. Any failure to make timely and adequate social welfare contribution for its employees may trigger an order of correction from competent authority requiring the employer to make up the full amount of such overdue social welfare contribution within a specified period of time, and the competent authority may further impose fines or penalties.

During the Track Record Period, we did not pay social insurance and housing provident fund in full for our employees. Also, we engaged third-party human resources agencies to pay on our behalf social insurance premium and housing provident funds for some of our employees during the Track Record Period. As a result, 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. 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 U.S. and international trade policies, particularly with regard to China, may cause disruptions to our clinical development, drug manufacturing processes and other aspects of our business and operations.

The U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. It remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade agreements, the imposition of tariffs on goods imported into the U.S., tax policy related to international commerce, or other trade matters. It is unknown whether new tariffs will be imposed, or whether new laws and regulations will be enacted, or the effect that any such actions would have on us or our industry. While we have not commenced commercial sales of drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and disrupt our drug development and the manufacturing of our drug candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, the demand for and competitiveness of our drugs, or prevent us from selling our drugs in certain countries. If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

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. Our operations may be under the threat of natural disasters, such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, other factors beyond our control, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness, including the COVID-19 pandemic, or other adverse public health developments in China or elsewhere could materially disrupt our business and operations. For example, the extent to which COVID-19 affects our results of operations going forward will depend on the future developments of the pandemic. These uncertain and unpredictable factors include, but are not limited to, adverse effects of the pandemic on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners and CROs. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening other risks described in this document, including those relating to our ability to initiate or continue clinical trials for our drug candidates. Moreover, since there has been a significant increase in demand for electricity supply in the PRC in August 2022, certain provinces have implemented power rationing measures to conserve fuel stocks and reduce energy intensity, including Sichuan province. As of the Latest Practicable Date, our operations had not been materially affected and our facilities had not experienced any power outage as a result of the recent power rationing measures. However, we cannot assure you that we would not experience significant power shortage or outages under similar circumstances in the future.

Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

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

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. For more details, please see "Business – Insurance." Although we maintain insurance coverage for adverse events in our 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 industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. Although we believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in the PRC, 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.

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, manufacturing facilities and storage spaces. 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 failed to register all of the lease agreements as tenant, which were primarily used as our offices, manufacturing facilities and storage spaces. 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. In addition, as our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

Our property valuation is based on certain assumptions which, by their nature, are subjective and uncertain and may materially differ from actual results.

The property valuation report prepared by Cushman & Wakefield Limited, an independent property valuer, set out in the Property Valuation Report set out as Appendix VI to this document with respect to the appraised values of our properties is based on various assumptions, which are subjective and uncertain in nature. The assumptions that Cushman & Wakefield Limited used in the property valuation report include that the seller sells the property interest in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the value of the property interest. Certain of the assumptions used by Cushman & Wakefield Limited in reaching the appraised value of our properties may be inaccurate or unreasonable. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the appraised value of our properties may differ materially from the price we could receive in an actual sale of the properties in the market and should not be taken as their actual realizable value or an estimation of their realizable value. You should not place undue reliance on such values attributable to these properties as appraised by Cushman & Wakefield Limited.

Disruptions in the 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 including, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms.

In addition, concerns over the recent Russian-Ukraine conflicts, unrest and terrorist threats in the Middle East and other territories, 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. See also "– Risks Relating to Our Operations – We may be exposed to the risks of conducting business globally."

RISKS RELATING TO DOING BUSINESS IN CHINA

Changes in China's economic, political, social conditions as well as government policies could adversely affect our business, financial condition, results of operations and prospects.

Due to our extensive operations in China, our business, financial condition, results of operations and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

While China's economy has experienced significant growth over the past decades, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development, such as allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, and providing preferential treatment to particular industries or companies. In addition, the PRC government continues to play a significant role in regulating industry development by imposing relevant industrial policies. Some of these measures may benefit the overall China's economy or our industry, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past, the PRC government implemented certain measures, including interest rate adjustment, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

We are required to comply with certain filing requirements and other procedures with the China Securities Regulatory Commission or other PRC regulatory authorities in connection with this [REDACTED], and failure to do so may result in negative consequences.

On December 24, 2021, the CSRC released the Administrative Provisions of the State Council on the Overseas Offering and Listing of Securities by Domestic Companies (Draft for Comments) (《國務院關於境內企業境外發行證券和上市的管理規定(徵求意見稿)》) (the "Draft Listing Administrative Provisions") and the Administrative Measures for the Recordation of Overseas Offering and Listing of Securities by Domestic Companies (Draft for Comments) (《境內企業境外發行證券和上市備案管理辦法(徵求意見稿)》) (the "Draft Listing Measures", together with the Draft Listing Administrative Provisions, the "New Draft Overseas Listing Rules"), both of which had a comment period that expired on January 23, 2022.

On February 17, 2023, after a year-long market consultation of the New Draft Overseas Listing Rules, the CSRC released the Trial Administrative Measures for 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 "Trial Measures"), together with five interpretative guidelines thereof, which will become effective on March 31, 2023 (the "Implementation Date"). The Trial Measures, upon the Implementation Date, will comprehensively improve and reform 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 by adopting a filing-based regulatory regime. According to the Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC within three (3) working days after submitting the listing application documents to the overseas supervisory authorities and report relevant information. On the same date, the CSRC also released the Notice on the Arrangements for the Filing Management of Overseas Listing of Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which stipulated that prior to the Implementation Date, the CSRC would carry on its works on a normal basis pursuant to relevant regulations for the accepted applications for administrative approval for the overseas securities listing, under which circumstance if such companies could not obtain administrative approval prior to the Implementation Date, these companies shall complete the filing procedures with the CSRC.

As of the Latest Practicable Date, our Company had submitted overseas [**REDACTED**] application to the CSRC pursuant to the currently effective rules and regulations and obtained the acceptance letter. In accordance with such currently effective rules and regulations, we shall obtain an approval letter from the CSRC for the [**REDACTED**], following such acceptance letter. However, there remains uncertainty as to our applicable regulatory procedures under the Trial Measures and how long such regulatory procedures may take.

The legal protections available to you under the PRC legal system may be limited. It may be difficult to effect service of legal process and enforce judgments against us and our management.

A majority of our directors and our senior management personnel reside within the PRC, and a majority of their assets are located within the PRC. As a result, it may not be possible to effect service of process within certain jurisdictions outside the PRC upon us or most of our directors and senior management. Furthermore, the PRC does not have treaties providing for the reciprocal enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in China or Hong Kong of judgments of a court obtained in the United States and any of the other jurisdictions mentioned above may be difficult or impossible.

On July 14, 2006, the Supreme People's Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by Courts of the Mainland and the Hong Kong Special Administration Region Pursuant to Choice of Court

Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the "Arrangement"). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case pursuant to a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. It is not possible to enforce a judgment rendered by a Hong Kong court in China if the parties in dispute have not agreed to enter into a choice of court agreement in writing. In addition, the Arrangement has expressly provided for "enforceable final judgment", "specific legal relationship" and "written form."

On January 18, 2019, the Supreme People's Court and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》) (the "New Arrangement"), which seeks to establish a mechanism with further clarification on and certainty for reciprocal recognition and enforcement of judgments in a wider range of civil and commercial matters between Mainland China and Hong Kong. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People's Court and the completion of the relevant legislative procedures in Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in Mainland China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

Under the New Arrangement, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the effective judgments in civil and commercial cases subject to the conditions set forth in the New Arrangement. Although the New Arrangement has been signed, the outcome and effectiveness of any action brought under the New Arrangement may still be uncertain. We cannot assure you that an effective judgment that complies with the New Arrangement can be recognized and enforced in a PRC court.

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

A large portion of our operations are conducted in China, and are governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In the late 1970s, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. In particular, because these laws, rules and

regulations are relatively new and may give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and binding interpretation, the enforcement of these laws, rules and regulations involve uncertainties.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the "Scientific Data Measures"), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term "state secret" is not clearly defined, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

More stringent restrictions on the remittance of Renminbi into and out of the PRC and governmental control over currency conversion may limit our ability to pay dividends and other obligations, and affect the value of your [REDACTED].

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

Under China's current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The PRC government may also at its discretion restrict access in the

future to foreign currencies for current account transactions. Since 2015, in response to China's declining foreign currency reserves, the PRC government has placed increasingly stringent restrictions on the convertibility of the Renminbi into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

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

Certain of our cash and cash equivalents and amounts due to related parties are denominated in foreign currencies, and are exposed to foreign currency risk. We recorded net foreign exchange gains of RMB16.9 million and RMB10.4 million for the year ended December 31, 2021 and the nine months ended September 30, 2021, respectively, and net foreign exchange losses of RMB38.8 million for the nine months ended September 30, 2022. The exchange rate of the Renminbi against the U.S. dollar and other foreign currencies fluctuates and is affected by, among other things, the policies of the PRC government and changes in China's and international political and economic conditions. It is difficult to predict how market forces or government policies may impact the exchange rate between the Renminbi and the Hong Kong dollar, the U.S. dollar or other currencies in the future.

There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which, together with domestic policy considerations, could result in a significant appreciation of Renminbi against the Hong Kong dollar, the U.S. dollar or other foreign currencies.

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

We are a PRC tax resident and we are subject to PRC tax on our global income, and the dividends payable to [REDACTED] and gains on the sale of our H Shares by our investors are subject to PRC tax.

As a PRC-incorporated company, under applicable PRC tax laws, we are subject to a tax of up to 25% on our global income. Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to different tax obligations with respect to dividends received from us or gains realized upon the sale or other disposition of our H Shares.

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

Non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not related to such establishments or premises are subject to PRC EIT at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, which may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the non-resident enterprise resides. Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including [**REDACTED**] and payments through [**REDACTED**]). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, payment of any such refund will be subject to the PRC tax authorities' verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by non-resident enterprise holders of H Shares through the sale or transfer by other means of H Shares.

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

The biopharmaceutical industry in China is highly regulated. Future changes in laws, regulations or enforcement policies in China could adversely affect our business.

Our operations are mainly conducted in the PRC. The biopharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the research and development, trials, approval, registration, manufacturing, packaging, licensing and marketing of new drugs and various other aspects of the operation of biopharmaceutical companies. Any violation of the relevant laws, rules and regulations may subject us to disputes, administrative sanctions, criminal sanctions and other legal proceedings. See "Regulatory Overview." In recent years, the regulatory framework in China regarding the biopharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in, or prevent the successful development or commercialization of, our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in the country. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our H Shares. An active [REDACTED] for our H Shares may not develop and the [REDACTED] and [REDACTED] of our H Shares maybe volatile.

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

The [**REDACTED**] and [**REDACTED**] of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business, results of operations and the [**REDACTED**] of the shares of other companies engaging in similar business may affect the [**REDACTED**] and [**REDACTED**] of our H Shares. In addition to market and industry factors, the [**REDACTED**] and [**REDACTED**] of our H Shares may be highly volatile for reasons specific to our business, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments and healthcare policies directly affecting us, fluctuations in our cash flows, investments and expenditures, relationships with our suppliers, movements

or activities of key personnel or actions taken by competitors, among others. Moreover, shares of other biopharmaceutical companies listed on the Stock Exchange have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in [**REDACTED**] not directly related to our performance.

Since there will be a gap of several days between [REDACTED] and [REDACTED] of our H Shares, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares when trading begins could be lower than the [REDACTED].

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

Our Controlling Shareholder have substantial influence over our Company and its interests may not be aligned with the interests of our other Shareholders.

Our Controlling Shareholder, Kelun Pharmaceutical, has substantial influence over our business, including matters relating to our management, policies and decisions regarding acquisitions, mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of directors and other significant corporate actions. Immediately after completion of the [**REDACTED**], assuming the [**REDACTED**] is not exercised, our Controlling Shareholder will hold (including direct and indirect shareholdings) approximately [**REDACTED**]% of the issued share capital in our Company. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a [**REDACTED**] of our Company and might reduce the [**REDACTED**] of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Controlling Shareholder may differ from the interests of our other Shareholders. We cannot assure you that our Controlling Shareholder will not exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

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

Prior to the [**REDACTED**], there has not been a public market for our H Shares. Future sales or perceived sales of significant amounts of our H Shares or conversion of the Unlisted Shares, if any, by specific Shareholders subject to certain regulatory requirements, after the [**REDACTED**] could result in a significant decrease in the prevailing [**REDACTED**] of our H Shares. Nevertheless, after these restrictions lapse or if they are waived, future sales of

significant amounts of our H Shares in the public market or the perception that these sales, or conversion of existing Unlisted Shares, if any, may occur could significantly decrease the prevailing [**REDACTED**] of our H Shares and our ability to raise equity capital in the future.

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or equity securities in the future.

The [**REDACTED**] of the H Shares is higher than the net tangible asset value per H Share immediately prior to the [**REDACTED**]. Therefore, [**REDACTED**] of the H Shares in the [**REDACTED**] will experience an immediate dilution. In order to expand our business, we may consider [**REDACTED**] and [**REDACTED**] additional Shares in the future. [**REDACTED**] of the H Shares may experience dilution if we [**REDACTED**] additional Shares in the future at a [**REDACTED**] which is lower than the net tangible asset value per Share at that time. Furthermore, we may [**REDACTED**] Shares through the employee incentive platforms, which would further dilute Shareholders' interests in our Company.

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

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

We have significant discretion as to how we will use the [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the [**REDACTED**] from the [**REDACTED**] in ways you may not agree with or that do not yield a favorable return to our Shareholders. We plan to use a significant portion of the [**REDACTED**] from the [**REDACTED**] for the following purposes:

- the research, development and commercialization of our Core Products, namely, SKB264 and A166;

- the research, development and commercialization of our other key products;

- the continued development of our proprietary technology platforms for ADCs technology platforms for ADCs, biologics and small molecules, and advance our other pipeline assets, and explore and develop new drug candidates;

- the expansion of our manufacturing facilities and quality control system to support the anticipated commercialization of our late-stage assets; and

- working capital and other general corporate purposes.

For more details, please see "Future Plans and [**REDACTED**]."

However, our management will have discretion as to the actual application of our [**REDACTED**]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the [**REDACTED**] from the [**REDACTED**].

Certain facts, forecasts and statistics in this document relating to the biopharmaceutical industry are derived from a third-party report or publicly available sources and may not be fully reliable.

Certain statistics, information and data contained in this document relating to China and elsewhere in the world, and the industry in which we operate have been derived from various official government publications or other third-party reports. In particular, we have extracted and disclosed in this document certain statistics, information and data from publications and other publicly available sources relating to the drugs and drug candidates of third parties and scientific research, theories and mechanisms. We have taken reasonable care in the reproduction or extraction of the official government publications and other third-party reports for the purpose of disclosure in this document. However, we cannot guarantee the quality or reliability of such source materials. They have not been prepared or independently verified by us, the [**REDACTED**] or any of their respective affiliates or advisers and, therefore, we make no representation as to the accuracy of such statistics, information and data, which may not be consistent with other information compiled within or outside the PRC. Due to possibly flawed or ineffective collection methods and analysis or discrepancies between published information and market practice, such statistics, information and data in this document may be inaccurate or may not be comparable to statistics, information and data produced with respect to other economies. Further, there is no assurance that they are stated or compiled on the same basis or with the same degree of accuracy as the case may be in other jurisdictions. In all cases, investors should give consideration as to how much weight or importance they should attach to or place on such facts.

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

Prior to the publication of this document, there has been coverage in the media regarding us and the [**REDACTED**], which contained among other things, certain financial information, projections, valuations and other forward-looking information about us and the [**REDACTED**]. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for the accuracy or completeness of such media coverage or forward-looking statements. We make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the media. We disclaim any information in the media to the extent that such information is inconsistent or conflicts with the information contained in this document. Accordingly, prospective [**REDACTED**] are cautioned to make their [**REDACTED**] decisions on the basis of the information contained in this document only and should not rely on any other information.