

## RISK FACTORS

*An investment in our Shares involves significant risks. You should carefully consider all of the information in this Document, including the risks and uncertainties described below, before making an investment in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In any such case, the market price of our Shares could decline, and you may lose all or part of your investment.*

*These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-looking Statements” in this Document.*

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

***We have incurred significant net losses since inception. We expect that we will continue to incur net losses for the foreseeable future and we may not be able to achieve or maintain profitability. Potential investors may lose substantially all of their investments in us given the high risks involved in our business.***

Investment in biotechnology companies is highly speculative. We have incurred substantial capital expenditures to date, and expect to continue to incur expenses related to clinical trials and pre-clinical studies. For the years ended December 31, 2021 and 2022, we had total comprehensive loss of RMB111.8 million and RMB92.0 million respectively. However, we cannot assure you that all of our product candidates will obtain regulatory approvals and/or become commercially viable. Our ability to generate significant revenue from our product candidates will depend primarily on the success of the regulatory approval, manufacturing, and commercialization of the product candidates, which is subject to significant uncertainty. Even if we obtain regulatory approval to market our product candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our product candidates, and our ability to achieve sufficient market acceptance.

The amount of our future net losses will depend, in part, on our future expenses resulted from costs and expenses incurred by our research and development programs and in relation to our operations, the cost of commercializing any approved products, our ability to generate revenues, and the timing and amount of milestone and other payments we make or receive with or through arrangements with third parties. We expect to continue to incur significant expenses

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## RISK FACTORS

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and losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue to advance the clinical trials and pre-clinical studies of our product pipeline;
- initiate pre-clinical, clinical or other studies for new product candidates;
- seek regulatory approvals for our product candidates to complete clinical development and commence commercialization;
- manufacture our product candidates for clinical trials and for commercial sale;
- develop and expand our commercialization team to commercialize any product candidates in our pipeline for which we may obtain regulatory approval;
- acquire or in-license other product candidates, intellectual property assets and technologies;
- incur costs to develop or manufacture product candidates under any collaboration or in-license agreements;
- maintain, protect, expand and enforce our intellectual property portfolio;
- attract and retain skilled personnel, and grant equity-settled awards to our employees under our share incentive schemes; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

***We had net cash outflows from our operating activities during the Track Record Period. We may need to obtain additional financing to fund our operations, and financing may not be available on terms acceptable to us, or at all. If we are unable to obtain sufficient financing, we may be unable to complete the development and commercialization of our product candidates.***

Our product candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since our inception. We had net cash used in our operating activities of RMB68.5 million and RMB99.6 million for the years ended December 31, 2021 and 2022, respectively. We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our product candidates, and launching and commercializing any approved product candidates for which we receive regulatory approval.

## RISK FACTORS

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To date, we have funded our operations primarily through the loans from shareholders and/or related parties and equity financings. Our existing capital resources may not be sufficient to enable us to complete all global development or commercially launch all of our current product candidates for the currently anticipated indications and to invest in additional product development programs, particularly where the anticipated commercialization of our product candidates is delayed or terminated, or if the expenses associated with drug development and commercialization increase substantially. If the capital resources available to us are insufficient to satisfy our cash requirements, we may seek additional funding through [REDACTED], debt financings, collaborations and licensing arrangements. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this section. 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. Our future funding requirements will depend on many factors, including:

- 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 product candidates;
- the preparation required for anticipated commercialization of our product 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 product candidates;
- the amount and timing of any profit sharing, milestone and royalty payments we receive from our future collaborators, if any;
- the progress, timing, scope and costs related to discovery and early development of additional product candidates;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- selling and marketing costs associated with any future product candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- cash requirements of any future development of other pipeline product candidates; and
- our headcount growth, incentive schemes and associated costs.

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## RISK FACTORS

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We cannot assure you that we will have sufficient financing to fund our operations on acceptable terms and in a timely manner, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, we may be required to delay, limit, reduce or terminate pre-clinical studies, clinical trials or other research and development activities or commercialization for one or more of our product candidates, and in turn will materially and adversely affect our business prospects.

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

We are a development-stage biotechnology company founded in 2016. Our operations to date have focused on raising capital, establishing our intellectual property portfolio, drug discovery and conducting pre-clinical studies and clinical trials of our product candidates. As of the Latest Practicable Date, we had no products approved for commercial sale and did not generate any revenue from product sales. We also have limited experience in commercial-scale manufacturing and sales and marketing of drugs. For these reasons, particularly in light of the rapidly evolving pharmaceutical industry, it may be difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown situations. If we do not address these risks and difficulties successfully, it could materially adversely affect our business, financial condition, results of operations and prospects. These factors present uncertainties and material risks to our commercial success and may cause potential investors to lose a substantial portion or all of their investment in our business.

***An impairment in the carrying value of intangible assets could have a material adverse effect on our financial condition and results of operations.***

We had intangible assets of RMB61.5 million and RMB63.8 million as of December 31, 2021 and 2022 respectively. Our intangible assets primarily consist of technical know-how, including a portfolio of our drug candidates (CPL-01, CPL-05 and CPL-07) and the technology platforms (PG-Depot and ClearSol) in-licensed from Latitude. The intangible assets with finite useful lives are amortized using the straight-line basis over the commercial lives of the underlying products, commencing from the date when the intangible assets are available for use, and the intangible assets with indefinite useful lives or not ready for use will not be amortized but tested for impairment annually either individually or at the cash-generating unit level. The impairment test would compare the recoverable amount of each of the cash-generating units to its carrying value. Determination of recoverable amount requires considerable judgment and is sensitive to inherent uncertainties and changes in estimates and assumptions. Declines in market conditions, weak trends in anticipated financial performance of reporting units or declines in revenue projections are examples of indicators that carrying values of intangible assets may not be recoverable, and in turn result in impairment losses. Any significant impairment losses recorded against our intangible assets could have a material adverse effect on our financial condition and results of operations.

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## RISK FACTORS

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***Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, other than on a pro rata basis to existing Shareholders, the percentage of ownership of our existing Shareholders in our Company, the earnings per Share and the net asset value per Share may be reduced, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

On October 15, 2021, Cali Nova and Cali Trading transferred 12,000,001 Shares and 6,181,819 Shares respectively to Cali Sigma at nil consideration, which constituted share-based payment to Mr. Chen Poe-Jou, our executive Director. In addition, pursuant to the share transfer agreement dated May 4, 2023 between Cali Trading and Bangzhao and share transfer agreement dated May 9, 2023 between Cali Sigma and Bangzhao (which were both amended on June 25, 2023), Cali Trading and Cali Sigma agreed to transfer 120,031,962 and 9,523,980 Shares respectively to Bangzhao for cash considerations of HK\$70,000,000 and HK\$5,523,908 respectively, which will constitute share-based payment to Mr. Lin, our executive Director upon completion. For details, see “History, Reorganization and Development – Corporate Development”. To further incentivize our employees and non-employees to contribute to us, we may grant share-based compensation in the future, subject to the requirements of the Listing Rules and other applicable laws and regulations. Issuance of additional Shares with respect to such share based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

## RISK FACTORS

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### RISKS RELATING TO OUR BUSINESS

#### Risks Relating to the Development of Our Product Candidates

*Our business and financial prospects depend substantially on the success of our product candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals or achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.*

Our business will depend on our ability to successfully complete the development of our product candidates, obtain necessary regulatory approvals, and manufacture and commercialize our product candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing product candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our product candidates. The success of our product candidates will depend on several factors, including but not limited to:

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- sufficient resources to acquire or discover additional product candidates and successful identification of potential product candidates based on our research or business development methodology or search criteria and process;
- obtaining sufficient supplies of any drug products that are used in combination with our product candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our product candidates;
- establishing sufficient commercial manufacturing capabilities, either by making arrangements with CMOs, expanding our existing facilities and/or building new facilities ourselves;
- the performance by CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;

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## RISK FACTORS

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- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- obtaining and maintaining favorable governmental and private reimbursement from third-party payers for drugs, if and when approved;
- success in competing with other product candidates and drugs; and
- continued acceptable safety profile of our product candidates following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to develop, obtain approval for and/or to successfully commercialize our drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

***If the FDA does not conclude that certain of our product candidates, currently CPL-05 and/or CPL-07, satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.***

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (“**FDCA**”). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. We submitted the IND application for CPL-01 to FDA pursuant to the 505(b)(2) regulatory pathway in June 2019 and obtained FDA acknowledgement to proceed with the Phase IIa clinical trial in July 2019. However, if the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our other drug candidates, currently CPL-05 and CPL-07, as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product



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## RISK FACTORS

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candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA’s interpretation of Section 505(b)(2) to allow reliance on the FDA’s prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA’s interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. In addition, we expect that our competitors may file citizens’ petitions with the FDA in an attempt to persuade the FDA that our product candidate, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Moreover, the FDA adopts an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if such 505(b)(2) application does not rely on the previously approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA’s new interpretation, approval may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate sufficient revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

***Results of earlier studies and trials may not be predictive of future trial results.***

The results of pre-clinical studies and early clinical trials may not be predictive of the success of later phase clinical trials, and successful initial or interim results of a clinical trial do not necessarily predict successful final results. Our product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. Our future clinical trial results may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit.



## RISK FACTORS

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As our product candidates are developed through pre-clinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives.

***We may allocate our limited resources to pursue a particular product candidate or indication and fail to capitalize on product 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 product candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other product 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 product candidates for specific indications may not yield any commercially viable products. 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 collaboration, licensing or other royalty arrangements in cases in which 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 product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

***Clinical development involves a lengthy and expensive process with an uncertain outcome.***

To obtain regulatory approval for the sale of our product candidates, we are required to conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement, and can take years to complete, with uncertainty as to outcome. Failure can occur at any time during the clinical trial process. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication.

We may experience numerous unexpected events during, or as a result of, clinical trials and pre-clinical studies that could delay or prevent our ability to receive regulatory approvals for the development and commercialization of our product candidates, including but not limited to situations whereby:

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

## RISK FACTORS

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- we might have to suspend or terminate clinical trials or pre-clinical studies of our product candidates for various reasons, including a finding of unexpected characteristics or a finding that participants are being exposed to unacceptable health risks (including deaths in the worst case scenario);
- our product candidates may lack meaningful clinical responses or the participants may be 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 and may vary significantly among different CROs and hospitals as trial centers;
- we may encounter various manufacturing issues, including inability to reach agreements on acceptable terms with CMOs, delay in constructing our new manufacturing facilities or expanding our existing facilities, problems with manufacturing, supply quality, or obtaining sufficient quantities of our product candidates for use in a clinical trial;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon certain drug development programs;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- our CROs, CMOs, and other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons such as non-compliance with regulatory requirements;
- the costs of clinical trials of our product candidates may be substantially higher than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and

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## RISK FACTORS

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- our product candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

Any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that drug candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to: (i) the size and nature of the patient population; (ii) the patient eligibility criteria defined in the protocol; (iii) the size of the study population required for analysis of the trial’s primary endpoints; (iv) the proximity of patients to trial sites; (v) the design of the trial; (vi) our ability to recruit clinical trial investigators with the appropriate competencies and experience; (vii) 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; (viii) our ability to obtain and maintain patient consents; (ix) the risk that patients enrolled in clinical trials will not complete a clinical trial; and (x) the availability of approved therapies that are similar in mechanism to our product candidates.

In addition, our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. As the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. If we experience delays in the completion of, or even termination of, any clinical trial of our product candidates, the requisite regulatory approvals and then commercialization of our future drug products will be similarly delayed or adversely affected. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and materially adversely affect our ability to advance the development of our product candidates, which in turn could materially adversely affect our business, financial condition, results of operations and prospects.

## RISK FACTORS

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

To obtain regulatory approval for the commercialization of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans for their proposed indications. If the results of clinical trials of our product candidates are not positive or only modestly positive for proposed indications or if they raise safety concerns, we may: (i) be delayed in obtaining regulatory approval for our product candidates, or not obtain regulatory approval at all; (ii) be required to add labeling statements, or be required to create a medication guide outlining the risks of the side effects for distribution to patients; (iii) be required to develop risk evaluation and mitigation strategies and plans to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools; (iv) not obtain regulatory approval for all the proposed indications as intended; (v) be subject to additional post-marketing testing requirements or restrictions on how the drug is distributed or used; (vi) be sued or held liable for injury caused to individuals exposed to or taking our product candidates; (vii) be unable to obtain reimbursement for use of the drug; and (viii) have the drug removed from the market after obtaining regulatory approval.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, results of operations and prospects.

***We may not be successful in developing, enhancing or adapting to new technologies and methodologies.***

We must keep pace with new technologies and methodologies to maintain our competitive position. Our research and development expenses were RMB62.9 million and RMB84.2 million in 2021 and 2022, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in drug development, which are capital and time intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market or obtain any patent or other intellectual property protection for such new or enhanced products. Any failure to do so may make our technologies obsolete, which could harm our business and prospects.

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## RISK FACTORS

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

We cannot guarantee that we will be successful in identifying potential product candidates in the future to sustain our growth. Research programs to identify new product candidates and targets and to pursue the development of our product candidates for additional indications require substantial technical, financial and human resources without guaranteed ultimate success. For example, we have two in-licensed research and development platforms, which we believe enable us to design, evaluate and select optimal candidates and continue to enrich our pipeline. However, we cannot guarantee that we will be successful in identifying potential product candidates in the future to sustain our growth. Our research programs may initially show promising results in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to the following factors:

- the research methodology used may not be successful in identifying potential indications and/or new product candidates;
- potential product candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired efficacy; and
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that our internal research programs will lead to identification of new product candidates or additional therapeutic opportunities for our product candidates or development of suitable potential product candidates, which could materially adversely affect our future growth and prospects.

***Approved product candidates may become subject to unfavorable pricing regulations in China, which could harm our business.***

We intend to seek approval to market our product candidates primarily in the United States and China. In China, the pricing of drugs is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of any of our future approved product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payers for drugs and may be affected by existing and future health care reform measures.

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## RISK FACTORS

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In China, the Ministry of Human Resources and Social Security (the “MHRSS”) and National Healthcare Security Administration (the “NHSA”), or provincial or local human resources and social security authorities, review the inclusion or removal of drugs from the China’s National Drug Catalogue 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名錄》), or the National Reimbursement Drug List (the “NRDL”), or provincial or local medical insurance catalogs for the Provincial Reimbursable Drug List, (the “PRDL”) 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 product candidates will be included in the NRDL or the PRDL. Products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our product candidates have historically been more limited on their inclusion in the NRDL due to the affordability of the government’s basic medical insurance.

If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or the PRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive. Additionally, even if the MHRSS, the NHSA or any of their local counterparts accepts our application for the inclusion of our products in the NRDL or the PRDL, 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 or the PRDL.

See also “– Risks Relating to Our Business – Risks Relating to Extensive Government Regulation – Even if we are able to commercialize our approved product candidates, we may face uncertainties from national, provincial or other third-party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.”

***We face substantial competition, which may result in others discovering, developing and commercializing products before or more successfully than our product candidates.***

The development and commercialization of new drugs is highly competitive. We face competition (from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide) with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete directly with companies that focus on 505(b)(2) pathway, and companies dedicating their resources to novel forms of therapies for peri-operative pain and inflammatory conditions. Many of these competitors are attempting to develop products for our target indications. We face the risk that our competitors will develop a competing product using the same 505(b)(2) pathway that we intend to pursue. As of the Latest Practicable Date, we had two granted patents and three patent applications in relation to our Core Product, CPL-01, and one patent application in relation to CPL-05, respectively. As the research and development of CPL-07 is in the early stage, we plan to file relevant patents for it in the future. While we expect to have patent protection for all of our product candidates, in the event that following FDA approval of our product candidates we fail to

## RISK FACTORS

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obtain patent protection for some of our product candidates, our competitors may seek to develop a competing product pursuant to the 505(j) pathway, which is an abbreviated pathway used for the regulatory approval of generic product candidates. With the proliferation of new drugs and therapies in these areas, we expect to face increasingly intense competition as new technologies become available. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

There are products already approved for all of the indications we are targeting. Many of these approved products are well established therapies and are widely accepted by physicians, patients and third-party payors. This may make it difficult for us to achieve our business strategy of replacing existing products with our product candidates. In addition, where we are able to offer benefits over existing products offered by our competitors, those competitors may reformulate their drugs in a manner that mimics the benefits offered by our product candidates. Consequently, our commercial operations face significant direct competition and our competitors may develop products that are similar to ours and perhaps safer, more effective, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our inability to successfully compete could negatively impact our business and results of operations.

***Our competitors may obtain FDA or other regulatory approval for comparable products more rapidly than we may obtain approval for ours, and the risk of our competitors doing so may lead us to develop drug candidates without disclosing certain information with regard to such candidates.***

The FDCA provides three years of marketing exclusivity for an NDA (including a 505(b)(2) NDA), or supplement to an existing NDA (including a 505(b)(2) NDA), if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, (e.g. for new indications, dosages, strengths or dosage forms of an existing drug). Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. As a result, many of our competitors have the ability to bring a product candidate to market more rapidly than we can and depending on the nature of their product candidate they could substantially delay the introduction of our product candidate into the market if their product qualifies for the market and data exclusivity provisions under the FDCA. In order to preserve any competitive advantage, we will, at times, make the decision to pursue a product candidate for which we will not disclose the API, dosage or reference drug until such time as we believe that any competitive advantage would not be materially compromised by public disclosure of such information, which in some cases may be as late as our receipt of marketing approval from the FDA. Our business currently depends on our ability to bring our product candidates to market in a manner that preserves our perceived competitive advantage and any loss of that competitive advantage could negatively impact our business and results of operations.



## RISK FACTORS

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### Risks Relating to Extensive Government Regulations

*All material aspects of the research, development, manufacturing and commercialization of our product candidates are heavily regulated.*

All jurisdictions in which we intend to develop and commercialize our product candidates regulate these activities in great depth and detail. We intend to initially focus our activities in the United States and China while pursuing global opportunities. The pharmaceutical industries in these jurisdictions are subject to comprehensive regulation for the development, approval, manufacturing, marketing, sales and distribution of products.

Any recently enacted and future legislations may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our product candidates, and affect the pricing of our product candidates. Changes in government regulations or in practices relating to the pharmaceutical industries, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors, or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects.

In many countries or regions where a drug is intended to be ultimately sold, such as the United States and China, 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 FDA, or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, or their clinical trials are filed as part of a NDA, BLA or other filings to seek marketing approval. These regulatory authorities may conduct scheduled or unscheduled periodic inspections of our facilities to monitor our regulatory compliance. Although we passed all the inspections and obtained clearance in relation to discovery and development, if applicable, from the regulatory authorities in all material respects during the Track Record Period, we cannot assure you that we will be able to do so going forward. Any failure to comply with existing regulations and industry standards could result in fines or other punitive actions against us, and the disqualification of data for submission to regulatory authorities, 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 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. For example, if we or our CROs were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

## RISK FACTORS

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In addition, 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.

***The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are unable to obtain without undue delay any regulatory approval for our product candidates in our targeted markets, our business may be materially and adversely affected.***

Significant time, effort and expense are required to bring our product candidates to market in compliance with the regulatory process, and we cannot assure you that any of our product candidates will be approved for sale. The time required to obtain approvals from the NMPA, the FDA, and other comparable regulatory authorities is unpredictable but, for the new drugs, it may typically take up to 15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. In addition, it is not uncommon that the NMPA, the FDA, or a comparable regulatory authority may require more information, including additional analysis, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our product candidates will be approved for sale in those jurisdictions. Additional time, effort and expense may be required to bring our product candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes. Our product candidates could fail to receive regulatory approval in a timely manner for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that our drug candidate is safe and potent for its proposed indications;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;

## RISK FACTORS

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- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA, and other comparable regulatory authorities may also change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Any delays in completing our clinical trials will slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, our failure to comply with the regulatory requirements to obtain the regulatory approvals could result in governmental agencies taking actions in the relevant jurisdictions, including imposing fines and penalties on us, preventing us from manufacturing or selling our future products, upon regulatory approval, bringing criminal charges against us, delaying the introduction of our new products into the market, recalling or seizing our future drug products, and/or withdrawing or denying approvals or clearances for our future drug products, and we could also be subject to civil liabilities for this reason. If any or all of the foregoing were to occur, we may not be able to meet the demands of hospitals and physicians which use our future drug products and they may cancel orders or purchase products from our competitors, which eventually may harm our business, financial condition and prospects significantly.

***Any failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.***

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic

## RISK FACTORS

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renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

***Even after we obtain regulatory approval for the marketing and distribution of our product candidates, our future products will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our future approved pharmaceutical products.***

If any of our product candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities in China, the United States, and other jurisdictions. As such, we are and will be subject to continual review and inspections by the regulators for their assessment of our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA, the FDA or other comparable regulatory authorities.

Drugs may be marketed only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, the FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The NMPA, the FDA, or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our product candidates or following approval. In addition, if the NMPA, the FDA, or a comparable regulatory authority approves our product candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacture Practices (“cGMP”) and Good Clinical Practice (“GCP”), for any clinical trials that we conduct post-approval. Accordingly, we and others we work with must continue to expend time, money and efforts in all areas of regulatory compliance, including manufacturing, production and quality control.

## RISK FACTORS

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We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China, the United States or other jurisdictions, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

***Adverse events caused by our product 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.***

Undesirable adverse events caused by our product candidates, or caused by our product candidates when used in combination with other drugs, could potentially cause significant negative consequences, including but not limited to:

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of our product candidates;
- regulatory authorities may order us to cease further development of, or delay or even deny approval of, our product candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug, issue safety alerts or other communications containing warnings or other safety information of such approved drug, or impose other limitations on such approved drug;
- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to change the way the drug candidate is administered, or conduct post-market studies;
- we could be subject to litigation proceedings and held liable for harm caused to patients exposed to or taking our product candidates may suffer from adverse events related to the treatment and patients;

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## RISK FACTORS

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- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- the costs of clinical trials of our product candidates may be substantially higher than anticipated;
- the product may become less competitive;
- we could be required to recall our product candidates and be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could significantly harm our business, results of operations and prospects.

***Even if we are able to commercialize our approved product candidates, we may face uncertainties from national, provincial or other third-party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for therapeutic products vary widely from jurisdiction to jurisdiction. We intend to seek approval to market our product candidates in the United States and China, and in other jurisdictions. In the United States and China, the pricing and reimbursement of drugs is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved product 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 MHRSS and the NHSA, or provincial or local human resources and social security authorities, review the inclusion or removal of drugs from the NRDL, or the PRDL, 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 product candidates will be included in the NRDL or the PRDL. Products included in the NRDL or the PRDL are typically generic and essential drugs. In particular, the PRC government has implemented significant reforms of the pharmaceutical industry in recent years and may enforce additional measures in the future



## RISK FACTORS

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which may adversely affect our pricing strategy drugs. Even if our product candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates.

In the United States, 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 product candidates. Patients are unlikely to use any of our future approved product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs.

Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any approved product 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 product candidates that we commercialize. Obtaining or maintaining reimbursement for our future approved product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidates that we successfully develop.

There may be significant delays in obtaining reimbursement for approved product candidates, and coverage may be more limited than the purposes for which the product candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved product candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.



## RISK FACTORS

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

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the 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. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officers 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, results of operations or prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protect regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients’ privacy, privacy leakage incidents might not be avoided due to hacking activities, human error, employee misconduct or negligence or system breakdown. We also cooperate with third parties including principal investigators, hospitals, CROs, CMOs and other third-party contractor 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. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. 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.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. Such regulatory requirements on data privacy are constantly evolving and can be subject to varying interpretations, or significant changes, resulting in uncertainties about the scope of our responsibilities in that regard. For example, the PRC Data Security Law (《中華人民共和國數據安全法》), which took effect in September 2021, provides for a security review procedure for the data activities

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## RISK FACTORS

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that may affect national security. The PRC Personal Information Protection Law (《中華人民共和國個人信息保護法》), which took effect from November 2021, provides the circumstances under which a personal information processor could process personal information and the requirements for such circumstances. The Personal Information Protection Law clarifies the scope of application, the definition of personal information and sensitive personal information, the legal basis of personal information processing and the basic requirements of notice and consent. The Measures for Cybersecurity Review (《網絡安全審查辦法》), which came into effect on February 15, 2022, provides that critical information infrastructure operators that purchase network products and services and data processing operators engaging in data processing activities that affect or may affect national security must be subject to the cybersecurity review. The Measures for Cybersecurity Review further elaborates the factors to be considered when assessing the national security risks of the relevant activities, including, among others: (i) the risk of core data, important data, or a large amount of personal information being stolen, leaked, destroyed, and illegally used or exited the country, and (ii) the risk of critical information infrastructure, core data, important data, or a large amount of personal information being affected, controlled, or maliciously used by foreign governments after the [REDACTED]. Drafts of some of these measures have now been published, including the Data Security Management Measures (Draft for Comments) (《數據安全管理辦法(徵求意見稿)》) published in May 2019, and Measures on Security Assessment for Individual Information Cross-border Transfer (Draft for Comments) (《個人信息出境安全評估辦法(徵求意見稿)》) in June 2019, which may, upon enactment, require security review before transferring human health-related data out of China. The Regulations of the PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) which became effective on July 1, 2019 stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources (“HGR”) at clinical institutions without export of HGR materials. However, the two parties shall file the type, quantity and usage of the HGR to be used with the administrative department of science and technology under the State Council before clinical trials. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of our HGR samples and associated data and subject us to administrative fines, penalties and negative publicity.

In addition, there are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as “**protected health information**”) and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analysis and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks

## RISK FACTORS

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by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

***Changes in the United States and international trade policies, particularly with regard to China, may adversely impact our business and operating results.***

We intend to conduct clinical trials in parallel separately in the United States and China for some of our product candidates. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions, including the United States. In particular, China’s political relationships with the United States may affect our operations and the prospects of maintaining existing or establishing new collaboration partnerships in the United States.

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 actions, if any, the U.S. government will take with respect to other existing international trade agreements. It is also unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. While we have not started commercialization of any of our product candidates and our current operations do not involve import or export of goods between China and the United States, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future drug products, the competitive position of our future drug products, the hiring of scientists and other research and development personnel,

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## RISK FACTORS

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and import or export of raw materials in relation to drug development, or prevent us from selling our future drug products in certain countries. There can be no assurance that existing and potential collaboration partners will not alter their perception of us or their preferences as a result of such adverse changes in the relationship between China and the United States. If any new tariffs, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

*If efficacy or other issues arise with any of our in-licensed technology platforms, we may be unable to develop our product candidates and may experience significant regulatory delays.*

We plan to develop our drug candidates based on our in-licensed technology platforms, PG-Depot and ClearSol. If efficacy or other issues arise with these technology platforms, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, the intellectual properties of the in-licensed technology platforms may be subject to priority disputes or to inventorship disputes and similar proceedings. In the event that we or Latitude are involved in any of these proceedings, we may not be able to complete clinical development of our drug candidates on our current timeline or at all.

### **Risks Relating to Manufacturing of Our Product Candidates**

*The manufacturing of pharmaceutical products is a highly exacting and complex process, and our business could suffer if we encounter problems in manufacturing our future products.*

As our product candidates have not been approved for commercialization yet, we have no experience in large-scale manufacturing of our product candidates for clinical or commercial use and we have limited experience in managing the manufacturing process as we are currently relying on third parties, such as CMOs, in our manufacturing process for the clinical supply of our product candidates.

The manufacturing of pharmaceutical products is a highly complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, changes in product specification, low quality or insufficient supply of raw materials or our future expansion of our manufacturing facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, advances in manufacturing techniques, physical limitations that could inhibit continuous supply and man-made or natural disasters and other environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to

## RISK FACTORS

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customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

In addition, we face additional manufacturing risks in relation to the CMOs we engage from time to time. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future, either relating to our third-party CMOs or on our manufacturing facilities we plan to build in the future. See “– If we encounter problems in manufacturing our products, our business and results of operations could be adversely affected.”

Manufacturing methods and formulation are sometimes altered through the development of product candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such alterations carry the risk that they will not achieve these intended objectives. Any of these alterations could cause the product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of product candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in drug approvals and jeopardize our ability to commence product sales and generate revenue.

We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA, the FDA or other comparable regulatory authorities standards or specifications, maintaining consistent and acceptable production costs, and 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 future drug 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.

Furthermore, the quality of our future drug products, including product candidates manufactured by us upon the completion of the construction of our new manufacturing facilities or by the CMOs for research and development purposes and for commercial use in the future, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in the CMOs or in our future manufacturing facilities, the quality and reliability of equipment used, the quality of manufacturing staff and related training programs and our ability to ensure that our employees and CMOs adhere to our quality control and quality assurance protocol. However, we cannot assure you that the quality control and quality assurance procedures of our Company and CMOs will be effective in consistently preventing and resolving deviations from our quality standards. We are, however, working with CMOs on improving our documentation procedures for quality control and quality assurance activities. Any significant failure or deterioration of

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## RISK FACTORS

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our quality control and quality assurance protocol could render our future drug products unsuitable for use, jeopardize any GMP 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.

***Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts.***

We currently rely on third parties, such as CMOs, in our manufacturing process for the clinical supply of our drug candidates.

We plan to build new manufacturing facilities and cooperate with third parties to construct such facilities in the future. We cannot assure you that we will not experience any disruptions to the third parties’ performance of their obligations, and there could be delays in completing and receiving regulatory approvals for our new manufacturing facilities. We may also encounter construction cost overruns. If the constructions of our manufacturing facilities or our production lines encounter unanticipated delays or incur additional expenses than expected, our manufacturing capacity of our product candidates may be limited, which would delay or limit our development and commercialization activities and our opportunities for growth. Our manufacturing facilities are required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, FDA, or other comparable regulatory authorities to ensure compliance with GMP regulations. Further, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot guarantee that we will be able to adequately follow and document our adherence to such cGMP regulations or other regulatory requirements. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our product candidates or their commercialization, if approved. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of our product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

In addition, to obtain FDA approval for our products in the United States, we would need to undergo strict pre-approval inspections of our future manufacturing facilities or manufacturing facilities of the CMOs for our produces. Historically, manufacturing facilities



## RISK FACTORS

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in China have had difficulty meeting FDA standards. When inspecting our manufacturing facilities, the FDA may cite cGMP deficiencies. Remediating deficiencies can be laborious, time consuming and costly. Moreover, the FDA will generally re-inspect the facility to determine whether the deficiency was remediated to its satisfaction, and may note further deficiencies during re-inspection. If we cannot satisfy the FDA as to our compliance with cGMP in a timely basis, the FDA marketing approval for our products and the commercialization of our drug candidates could be seriously delayed, which in turn could materially adversely affect our business, financial condition, results of operations and prospects.

*If we encounter problems in manufacturing our products, our business and results of operations could be adversely affected.*

While we currently rely on third parties, such as CMOs, in our manufacturing process for the clinical supply of our drug candidates, we plan to establish our internal manufacturing capabilities in the future. The continued operation of our production sites and our production safety may be substantially interrupted and materially and adversely affected due to a number of factors, many of which are outside of our control. These may include fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, or other natural disasters, as well as loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities or their vicinity and regulatory changes.

If the operation of any of our major production sites is substantially disrupted, we may not be able to replace the equipment or inventories at such facilities, or use different sites or a third party contractor to continue our production in a legal, timely and cost-effective manner or at all. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new sites or the expansion of our existing production sites, including changes in production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. As a result of disruption to any of our production sites or any problems in manufacturing our products, we may fail to fulfill contract obligations or meet market demand for our products, and our business, revenues and profitability could be adversely affected.



## RISK FACTORS

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### Risks Relating to Commercialization of Our Product Candidates

*Our product candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.*

The commercial success of our product candidates, upon regulatory approval, depends upon the degree of market acceptance each of such products achieves. Our product candidates, once approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other products to ours. If our product candidates (once approved and upon commercialization) do not achieve an adequate level of acceptance, the sales of our future drug products will be adversely affected, and we may fail to effectively market our product candidates (once approved and upon commercialization). The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, medical treatment centers and patients considering our drug;
- efficacy and safety of our product candidates;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payers and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities; and
- the effectiveness of our sales and marketing efforts.

## RISK FACTORS

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Once approved, if any product candidates that we commercialize fail to achieve market acceptance among physicians, patients, hospitals, medical treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our future approved product candidates achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced that are more favorably received than our product candidates, are more cost-effective or render our product candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved product candidates would materially adversely affect our business, financial condition, results of operations and prospects.

*We have limited experience in commercialization of pharmaceutical products. If we are unable to build or maintain sufficient sales and marketing capabilities, we may not be able to successfully create or increase market awareness of our product candidates or sell our future products, which will materially affect our ability to generate product sales revenue.*

As none of our product candidates have received regulatory approval for commercialization, we have limited experience in launching and commercializing our product candidates. As a result, our ability to successfully commercialize our product candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing product candidates.

As our product candidates are in the pre-clinical or clinical stage, we intend to build our in-house sales and marketing capabilities in the long term. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. There can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities to successfully commercialize any of our product candidates, if and when approved, and as a result, we may not be able to generate product sales revenue. In addition, we may pursue collaborative arrangements regarding the sales and marketing of our product candidates as appropriate. 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 depend upon the efforts of such third parties. We would 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 product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our product candidates.

## RISK FACTORS

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### Risks Relating to Our Intellectual Property Rights

*If we are unable to obtain and maintain adequate patent and other intellectual property protection for our product 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 develop and commercialize any of our product candidates or technologies would be materially adversely affected.*

Our success depends in large part on our ability to protect our proprietary technologies and product candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the product candidates and technology that we consider commercially important by filing patent applications in China, the United States and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we filed a provisional patent application and a non-provisional patent application relating to CPL-01 to the United States Patent and Trademark Office (“USPTO”) on March 31, 2021 and July 7, 2021, respectively. We also have two granted patents and filed one patent application relating to CPL-01 in China in 2022. For further information on our patent portfolio, see “Business – Intellectual Property.” If we or our collaborators are unable to obtain and maintain patent and other intellectual property protection with respect to our product candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. Furthermore, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The requirements for patentability differ in certain jurisdictions, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

## RISK FACTORS

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Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. As of the Latest Practicable Date, we had two granted patents and four pending patent applications. We cannot assure you that all of these patent applications will be granted. For further information on our patent portfolio, see “Business – Intellectual Property.” It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisers and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our collaborators were the first to file for patent protection of such inventions. Furthermore, China and, recently, the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. If a third party can establish that we or our licensors were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

We are primarily focused on protecting our intellectual property rights in our target markets, which are China and the U.S. Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Our intellectual property rights in certain jurisdictions may have a lessor or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in jurisdictions outside our target markets and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions in and into our target markets or other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patent or other intellectual property protection, but where enforcement rights are not as strong as those in markets such as the United States. 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.

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## RISK FACTORS

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Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions such as China. The legal system in these jurisdictions, particularly those in certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult 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 in these jurisdictions. Proceedings to enforce our patent and other intellectual property 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 and other intellectual property rights at risk of being invalidated or interpreted narrowly and 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 commercial advantage from the intellectual property that we develop or license. In addition, under the PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to China National Intellectual Property Administration (the “CNIPA”), for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

The patent position of pharmaceutical companies is generally highly uncertain, involving complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not issue as patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance and changes in either the patent laws or interpretation of the patent laws in China, the United States, and other jurisdictions. Any patents that we own or in-license may be challenged, narrowed, circumvented or invalidated by third parties. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

## RISK FACTORS

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The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the United States and other jurisdictions. We may be subject to a third-party submission of prior art to the USPTO challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may also become involved in opposition, derivation, revocation, re-examination, post-grant review, inter partes review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. In addition, a third party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. An adverse determination in any such submission, proceeding or litigation could put one or more of our owned or licensed patents at risk of being interpreted narrowly, invalidated, or ruled unenforceable and could allow third parties to commercialize products similar or identical to our technology or product candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges and proceedings may result in loss of patent rights or freedom to operate, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we cannot predict whether any of our technology or product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Although we have taken certain measures to obtain patent protection with respect to our major product candidates and technologies, any of our issued patents could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, for instance, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in China, the United States, or in other jurisdictions, even outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, interference proceedings, derivation,



## RISK FACTORS

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invalidation, revocation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer adequately cover and protect our product candidates.

***Even if we are able to obtain patent protection for our product candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.***

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For instance, in the United States, the expiration of a patent is generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority. In the United States, a patent’s term may be extended or adjusted to account for administrative delays during prosecution by the USPTO, in excess of a patent applicant’s own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. Even if patents covering our product candidates are successfully obtained, we may be open to competition from other companies once the patent has expired. Drug manufacturers 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. As a result, we may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The pending patent applications, if issued, for our product candidates are expected to expire on various dates as described in “Business – Intellectual Property” in this Document. 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 product candidates, patents protecting such product candidates might expire before or shortly after such product 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. Moreover, some of our patents and patent applications may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.



## RISK FACTORS

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***Our intellectual property portfolio comprises pending patent applications that have not yet been issued as granted patents, and if our pending patent applications fail to receive approval, our business will be adversely affected.***

A portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents. Patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. Specifically, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. Furthermore, China and, recently, the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented. In addition, under the PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Additionally, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisers and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. The patent application process is subject to numerous risks and uncertainties. We cannot assure you that any of our pending patent applications will result in issued patents, or even if issued, predict the breadth, validity and enforceability of the claims upheld in our and other companies’ patents. If our pending patent applications fail to receive approval, the costs spent in the process and the unavailability of patent protections on our research and development output could result in adverse effects on our business, financial condition and results of operations.

***We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.***

Competitors or other third parties may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other

## RISK FACTORS

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remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. 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. Therefore, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

Moreover, we may fail to detect infringement against our patents. Even if we detect infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce our patents against such third party.

Although we believe that we will conduct our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot assure you that there is no invalidating prior art of which we, our collaboration partners or their patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates, leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing third party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our product candidates.

In addition, although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaboration partners or other third parties have an

## RISK FACTORS

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interest in our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For instance, we may have inventorship disputes arise from conflicting obligations of employees, collaboration partners, consultants or others who are involved in developing our product candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship of our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail to defend any claim, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could lead to substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

*Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain, and we may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our product candidates or future products, or delay the commercialization of our product candidates in certain jurisdictions, as a result of such litigation or other proceedings relating to patent or other intellectual property rights.*

Our commercial success depends in part on our and our collaboration partners avoiding infringement, misappropriation, and other violations of the patents and other intellectual property rights of third parties. There may be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigations and other claims and proceedings involving patents and other intellectual property rights in the pharmaceutical industries generally. As the pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. We may also be subject to allegations by third parties of unfair competition, defamation or violation of their other rights. Even if we believe third-party intellectual property claims are without merit, we cannot assure you that a court would find in our favor on questions of infringement, validity, enforceability or priority, and it could have a material and adverse effect on our ability to develop and commercialize any of our product candidates and any other product candidates covered by the asserted third-party patents. The burden of successfully challenging a third-party claim may be high and require us to present clear and convincing evidence as to the invalidity of any such claim. There is no assurance that a court of competent jurisdiction would invalidate any such third-party claim.

If third parties, including the third parties that control the patents described above, bring successful claims against us for infringement, misappropriation or other violations of their intellectual property rights, we may be subject to injunctive or other equitable relief, which

## RISK FACTORS

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could prevent us from developing and commercializing one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim against us of infringement, misappropriation or other violation of intellectual property, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys’ fees in the case of willful infringement, pay royalties and other payments or redesign our infringing product candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Any such license might not be available on reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and we may be required to make substantial licensing and royalty payments. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent and other intellectual property infringement claims or to resolve disputes prior to litigation and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our Shares. Such litigations or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Application fees, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and patent applications are due to be paid to the CNIPA, USPTO and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and various non-U.S. governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We rely on our outside counsel and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with

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## RISK FACTORS

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the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

*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 or other third parties might be able to enter the market, which would have a material and adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Changes in patent laws of China, the United States or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.*

As is the case with other pharmaceutical companies, our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the United States, or other countries may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, the PRC Patent Law, which was amended on October 17, 2020 and became effective on June 1, 2021, provides patent linkage for pharmaceutical patents and patent terms extension for eligible innovative pharmaceutical patents. Patents owned by third parties may be extended, which may in turn affect our ability to commercialize our product candidates without facing infringement risks. The PRC Patent Law may enable the patent owner to submit applications for a patent term extension. The length of any such extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our product candidates non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For instance, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Assuming that other requirements for patentability are met, prior

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## RISK FACTORS

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to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States 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. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the United States and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility, narrowed the scope of patent protection available in certain circumstances, and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may affect the value of our patent rights or our other intellectual property rights. Any of the foregoing could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and the absence of patent linkage, patent term extension and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early competition for our product candidates in China.***

In the United States, the Federal Food Drug and Cosmetic Act, as amended by the law generally referred to as “Hatch-Waxman”, provides the opportunity for limited patent term extension. Hatch-Waxman permits a patent-term restoration that provides a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug 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. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. Depending upon the timing, duration and specifics of any FDA marketing approval process for any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. 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



## RISK FACTORS

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applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we fail to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and thus our revenue could be reduced.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the United States to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

The PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the owner of the patent for an innovative new drug that has been granted the marketing authorization in China to submit applications for a patent term extension of up to a maximum length of five years, in order to compensate the time required for the regulatory approval for the commercialization of such innovative new drug; provided that, the patent term of such innovative new drug shall not exceed a total of 14 years. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Furthermore, the PRC government has entered into the Economic and Trade Agreement Between the Government of the People’s Republic of China and the Government of the United States of America (中華人民共和國政府和美利堅合眾國政府經濟貿易協議) with the U.S. government in January 2020 which provides that the owner of the patent for an innovative new drug that has been granted the marketing authorization in China is entitled to request a patent term extension of up to five years; provided that, the patent term of such innovative new drug shall not exceed a total of 14 years from the date of marketing approval in China. If we are unable to obtain patent term extension, or the term of any such extension is less than that we request, our competitors or other third parties may obtain approval of competing products following our patent expiration. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

## RISK FACTORS

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

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our product 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, collaboration partners, outside scientific collaborators, sponsored researchers, CMOs, CROs, consultants, advisors and other third parties that have access to them. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. 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 product 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 thus our competitive position would be harmed.

Furthermore, many of our employees, consultants and advisors, including our senior management, were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and advisors, including each member of our senior management, executed proprietary rights and non-disclosure agreements in connection with such previous employment. We also have non-competition policies in place for our employees. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior 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

## **RISK FACTORS**

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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, we have entered into employee agreements with invention assignment provisions/invention assignment agreements with our employees and confidentiality agreements with our senior management and key members of our R&D team. Our standard employment contract is executed with each of our employees, contains an invention assignment clause, under which we own the rights to all inventions, technology, know-how and trade secrets resulting from work performed for us or relating to our business and conceived or completed during the course of such employee's work. However, we may fail in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, and, furthermore, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

In addition, our trade secrets and other proprietary or confidential information may become known or be independently developed by a third party, or misused by any collaborator or other third party to whom we disclose such information. Although we seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, confidential or proprietary information and other intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

Furthermore, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar product candidates or technology, without payment to us, or could limit the duration of the patent protection covering our product candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our product candidates without infringing third-party patent rights. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

## RISK FACTORS

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

As of the Latest Practicable Date, we had three registered trademarks, which may be the subject of a governmental or third-party objection and may not be registered successfully. We cannot assure you that any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our product candidates mature in the future, upon regulatory approval, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may be unsuccessful 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 or other third parties may adopt trade names or trademarks similar to ours, and impede 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. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

## RISK FACTORS

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

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 or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or any potential product candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we, current or any future collaboration partners, or any future licensors, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;
- we, current or any future collaboration partners, and any future licensors, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- patents that may be issued from our pending patent applications may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

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## RISK FACTORS

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### Risks Relating to Our Reliance on Third Parties

*We work with various third parties to develop our product candidates, such as those who help us conduct our pre-clinical studies and clinical trials. If we lose our relationships with these third-party service providers, or 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 product candidates, and our business could be materially harmed.*

We have worked with and plan to continue to work with third-party collaborators, such as CROs to monitor and manage data for our ongoing pre-clinical and clinical programs. We work with these parties to execute our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCP, which are regulations and guidelines enforced by the NMPA, the FDA and other comparable regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing pre-clinical studies, and clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may fail to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and delays, which can materially influence 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.



## **RISK FACTORS**

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We have entered into a License Agreement with Latitude. Our rights to develop and commercialize our drug candidates are subject to the terms and conditions of the license granted to us by Latitude. For more information regarding the License Agreement with Latitude, see “Business – Exclusive License of CPL Technologies from Latitude” in this Document. The License Agreement may be terminated by us with or without cause, and may be terminated by Latitude with cause. Upon termination of the License Agreement all licenses granted under the License Agreement, including all sublicenses granted by us, will automatically terminate with exception. Termination of the licenses provided for under the License Agreement or reduction or elimination of our rights under the License Agreement may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under the License Agreement, including our rights to important intellectual property or technology.

In addition, any dispute we may have regarding the License Agreement and the intellectual property subject thereto, such as the scope of rights granted under the License Agreement and other interpretation related issues; the inventorship, ownership and the right to use of inventions and know-how resulting from the independent or joint creation or use of intellectual property by the licensor and us and our partners; and enforceability of the License Agreement upon the licensor’s insolvency, may result in delay or even termination of the research, development or commercialization of the CPL-01, CPL-05 and CPL-07 or any other potential product candidates developed through PG-Depot and Clear-Sol, and may result in our inability to generate revenue in the foreseeable future and require us to seek additional funding in order to avoid delaying, reducing the scope of, or suspending, one or more of our research and development programs or clinical trials, thereby adversely affecting our business, financial condition, results of operation and prospects.

In addition, the License Agreement or other license agreements we may enter into, under which we license intellectual property or technology from the licensors, are usually complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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## RISK FACTORS

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*We depend on a stable and adequate supply of quality materials, research and development and manufacturing equipment from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.*

We procure raw materials and equipment for the development and manufacture of our product candidates from qualified suppliers. We also engage a limited number of reputable CROs to support our internal team in managing and conducting pre-clinical and clinical studies of our pipeline candidates in China and the United States. In addition, we engage reputable CMOs to manufacture drug candidates for pre-clinical and clinical supply. We expect to continue to rely on third parties to supply such materials and equipment as well as services for the research and development of our product candidates. See “Business – Raw Materials and Suppliers.”

In addition, we believe that adequate alternative sources for such supplies exist and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationship with alternative sources based on supply continuity risk assessment. However, there is a risk that, if supplies were interrupted, our business and results of operation would be materially harmed. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our product candidates.

Moreover, we require a stable supply of materials for our product candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of regulatory approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approval of our product candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time.

We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our future drug products and services sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability. Additionally, although we have implemented quality inspection on the materials before using them in the manufacturing process, we cannot assure you that we will be able to identify all of the quality issues.

## RISK FACTORS

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In addition, there is no assurance 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 materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our future drug products. The non-compliance of these third-party suppliers may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material and adverse effect on our business, financial condition and results of operation.

### RISKS RELATING TO OUR OPERATIONS

*We operate in a highly competitive and rapidly changing industry. If we fail to effectively compete with our competitors, our competitive position in our target markets may be undermined, our product candidates, if and when approved, may fail to be commercially successful and our business, financial condition, results of operations and prospects could suffer.*

The pharmaceutical industries in which we operate are highly competitive and rapidly changing. Large multinational pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions have commercialized or are commercializing or pursuing the development of products for which we are developing our product candidates.

Many of our competitors have substantially more developed commercial infrastructure, greater financial, technical and human resources than we do. Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our product candidates will still face competition based on safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price, patent position and other factors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or gain better acceptance for the same target markets as ours, which will undermine our competitive position. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome price competition and to be commercially successful. Disruptive technologies and medical breakthroughs may further intensify the competition and render our product candidates obsolete or non-competitive. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

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## RISK FACTORS

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***The loss of any key members of our senior management team or our inability to attract and retain highly skilled scientists, clinical and sales personnel could adversely affect our business.***

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

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

***We have significantly increased the size and capabilities of our organization since our inception, and we may experience difficulties in managing our growth. If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.***

We had 47 employees as of the Latest Practicable Date. As our development and commercialization plans and strategies evolve, we need to recruit a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- continuing to innovate and develop advanced technology in the highly competitive pharmaceutical market;
- managing our relationships with third parties, including suppliers and partners;
- identifying, recruiting, integrating, maintaining and motivating additional employees;

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## RISK FACTORS

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- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend in part on our ability to effectively manage our recent growth and any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisers and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisers and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively manage our anticipated growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, cause dilution to our Shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.***

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. For instance, we have received strong endorsement from Dashan, who has in-depth understanding of the new drug industry. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

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## RISK FACTORS

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- 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 product candidates and regulatory approval; and/or
- 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.

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.

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》) and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of PRC (《反壟斷法》) and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《關於經營者集中申報標準的規定》), or the “Prior Notification Rules” issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《實施外國投資者併購境內企業安全審查制度的規定》) (the “**Security Review Rules**”) issued by the MOFCOM specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns, and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the



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## RISK FACTORS

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above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval and filing processes, including obtaining approval or filings from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to security review, in which case our future acquisitions in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, could be subject to natural or man-made disasters or business interruptions. In addition, we partially rely on our third-party research institution collaborators for conducting R&D of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We may rely on third-party manufacturers to produce and process our products and product candidates in the future. Our ability to obtain supplies of our products and product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. For more details, see “– Risks Relating to Manufacturing of Our Product Candidates – If we encounter problems in manufacturing our products, our business and results of operations could be adversely affected.”

***Our operations and business plans may be adversely affected by natural disasters, health epidemics and pandemics, civil and social disruption and other outbreaks.***

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

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## RISK FACTORS

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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.

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.

***Increased labor costs could negatively affect our ability to operate efficiently and have a material and adverse impact on our revenues and profitability.***

Since our operations require the use of technical skills and know-how of our employees to a certain extent, our success depends in part on our ability to attract, retain and motivate a sufficient number of qualified employees. We have implemented a number of initiatives in an effort to attract, retain and motivate our qualified and competent staff. There is no assurance that these measures will be effective or that supply of skilled labor in local markets will be sufficient to fulfill our needs. Competition for competent and skilled labor is intensive in the industry. Our failure to hire and retain enough skilled employees could delay construction schedule of the works undertaken by us, the anticipated pre-clinical studies or clinical trials timeframe or receipt of regulatory approvals to commercialize our product candidates, or result in our expenses exceeding our initial budget. Any of the foregoing changes could have a material adverse effect on our business, profitability and prospects.

Further, as of the Latest Practicable Date, 80.9% of our workforce is employed in China. The average labor cost in China has been steadily increasing over the past years as a result of inflation, government-mandated wage increases and other changes in the PRC labor laws. Further changes in the labor laws, rules and regulations may be promulgated by the Chinese government in the future and our operations may be materially adversely affected if such laws, rules or regulations impose additional burden on the employers. The labor cost will continue to increase in the future which is in line with the economic growth in China. Competition for employees would require us to pay higher wages, which would result in higher labor costs.

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

We face an inherent risk of product and professional liability as a result of the clinical testing and any future commercialization of our product candidates inside and outside China and the United States. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of

## RISK FACTORS

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defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management’s time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; significant increase in insurance premium; and the inability to commercialize any approved drug candidate.

To cover such liability claims arising from clinical studies, we purchase clinical trial insurance in the conduct of our clinical trials. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

***Any future litigation, legal disputes, claims or administrative proceedings against us could be costly and time-consuming to defend and our reputation could be harmed.***

We may from time to time become subject to various litigation, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business or pursuant to governmental or regulatory enforcement activity, including but not limited to various disputes with or claims from our suppliers, customers, collaborators, business partners and other third parties that we engage for our business operations. Litigation to which we subsequently become a party might result in substantial costs and divert management’s attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings that may initially not appear to be of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved.

## RISK FACTORS

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Our insurance might not adequately cover claims brought against us, or at all, provide sufficient payments to cover all of the costs to resolve one or more such claims and might not continue to be available on terms acceptable to us. In particular, any claim could result in unanticipated liability to us if the claim is outside the scope of the indemnification arrangement we have with our collaborators, our collaborators do not abide by the indemnification arrangement as required, or the liability exceeds the amount of any applicable indemnification limits or available insurance coverage. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations or reputation.

If any verdict or award is rendered against us or if we settle with any third parties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. In addition, negative publicity arising from litigation, legal or contractual disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

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

We are subject to the anti-bribery laws of various jurisdictions, particularly in China and the U.S that generally prohibits companies and their intermediaries or employees from making payments to public officials for the purpose of obtaining or retaining business or securing any other improper advantage. As our business has expanded, the applicability of the applicable anti-bribery laws to our operations will increase. We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by government authorities, which may adversely affect our reputation. Although we have policies and procedures designed to ensure that we, our employees and our intermediaries comply with anti-bribery laws, there is no assurance that such policies or procedures will protect us against liability under such laws for actions taken by our employees and intermediaries with respect to our business or any businesses that we acquire. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. 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. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

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## RISK FACTORS

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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. 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 and results of operations.

***If our employees engage in bribery or corrupt practices or other improper conduct, we may be subject to liability and our reputation and business could be harmed. Additionally, any challenges to or investigations into our practices under these laws could generate negative publicity and could be costly to respond to, and thus could harm our business.***

We could be liable for actions taken by our employees that violate anti-bribery, anti-corruption and other related laws and regulations in China or other countries. The government authorities may seize the products involved in any illegal or improper conduct engaged in by our employees. We may be subject to claims, fines or suspension of our operations. Our brand and reputation, our sales activities or the price of our Shares could be adversely affected if the Group is associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our employees.

It is also possible that the PRC government could adopt new or different regulations affecting the way in which pharmaceuticals are sold to address bribery, corruption or other concerns. Although we are not aware of any such new or different regulations in this regard being adopted in China and other countries, any such new or different regulations could possibly increase the costs incurred by us in promoting pharmaceuticals or impose restrictions on sales and marketing activities, which could in turn increase our costs and adversely affect 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, which may negatively impact our research and development progress and overall operations.***

We operate in the pharmaceutical industry, which involves numerous operating risks and occupational hazards. We maintain insurance policies that are required under the laws and regulations of the PRC and the United States as well as based on our assessment of our operational needs and industry practice as of the Latest Practicable Date. Our principal insurance policies cover insurance for adverse events in clinical trials. However, we cannot assure you that the existing insurance coverage is sufficient to compensate for actual losses suffered or incurred. 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 and may negatively impact our drug development and overall operations.

## RISK FACTORS

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*Our internal information technology and other infrastructure, or those used by our partners or other contractors or consultants, may fail or suffer security breaches, which may require us to expend additional resources to protect our technology and information systems and could materially adversely affect our business, financial condition, results of operations and prospects.*

Despite the implementation of security measures, our information technology systems and those of our current or future partners, CROs, CMOs, consultants and other service providers or suppliers are vulnerable to damage from cyber-attacks, computer viruses, malicious codes, unauthorized access, employee theft or misuse, natural disasters, fire, power loss, terrorism, war, and telecommunication and electrical failures, among other things. 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 product 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 product candidates could be delayed. In addition, a security breach may result in the loss of, damage to, or public disclosure of personally identifiable information, and such an event could have serious negative consequences, including disputes, regulatory action, investigation, litigation, fines, penalties and damages, and time-consuming and expensive litigation, any of which could have a material adverse effect on our business, financial condition, results of operations, or prospects.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Since information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or suppliers that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have a material adverse impact on us and our business, including loss of data and damage to equipment, among other things. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues.



## **RISK FACTORS**

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We could be subject to risks caused by misappropriation, misuse, leakage, falsification, system malfunction or intentional or accidental release or loss of information maintained in the information systems and networks of us and our suppliers, including but not limited to personal information of our employees and patients. In addition, outside parties may attempt to penetrate our systems or those of our suppliers or fraudulently induce our personnel or the personnel of our suppliers to disclose sensitive information in order to gain access to our data or systems. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, results of operations, financial condition or prospects. If we experienced any such material system failure or security breach and interruptions in our operations, it could result in a material disruption of our development programs and our business operations, a breach of sensitive personal information or a loss or corruption of critical data assets including trade secrets or other proprietary information. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. If a material breach of our information technology systems or those of our suppliers occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated. As we engage in more electronic transactions with payers, suppliers and patients, and collect and store an increasing volume of data, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

## RISK FACTORS

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We may not have adequate insurance coverage to compensate for any losses associated with a system failure, any breach of our computer systems or other cybersecurity attack or any violation of any privacy laws or other obligations. Any breach or failure of our or our suppliers’ computer systems, information technology and other infrastructure could materially adversely affect our business, financial condition, results of operations and prospects.

***If our internal risk management and control system is not adequate or effective, and if it fails to detect potential risks in our business as intended, our business, financial condition and results of operations could be materially and adversely affected.***

We have an internal control system in place to monitor and control potential risk areas relevant to our business operations. However, due to the inherent limitations in the design and implementation of our internal control system, our internal control system may not be sufficiently effective in identifying, managing and preventing all risks if external circumstances change substantially or extraordinary events take place.

Further, integration of various business operations from potential future acquisitions may give rise to additional internal control risks that are currently unknown to us, despite our efforts to anticipate such issues. If our internal control system fails to detect potential risks in our business as intended, or is otherwise exposed to weaknesses and deficiencies, our business, financial condition and results of operations could be materially and adversely affected.

Our risk management and internal controls also depend on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct. If we fail to implement our policies and procedures in a timely manner, or fail to identify risks that affect our business with sufficient time to plan for contingencies for such events, our business, financial condition and results of operations could be materially and adversely affected, particularly with respect to the maintenance of our relevant approvals and licenses granted by the relevant authorities.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. 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.

## RISK FACTORS

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Further, we cannot eliminate the risk of accidental contamination, biological or chemical hazards or personal injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages and clean-up costs, and any liability could exceed our resources. We could also incur significant costs associated with civil or criminal fines and penalties. 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 workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

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

***If we use hazardous materials in a manner that causes injury, our research, development or production activities could be impaired and we may be subject to substantial fines, penalties or other liabilities.***

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

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

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

## RISK FACTORS

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*We are subject to the risks of doing business globally, including risks relating to political and economic instability and changes in diplomatic and trade relationships, which may materially and adversely affect our business and results of operations.*

Since we operate in China and the United States, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country’s or region’s political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- differences between national and local practice with respect to laws and regulatory requirements in a specific jurisdiction;
- difficulty of effective enforcement of contractual provisions in certain jurisdictions;
- concerns of local governments and regulators on our research and trial sites and on the relevant management arrangements;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management’s attention from the acquisition or development of product candidates or cause us to forgo profitable licensing opportunities in these geographies;
- occurrence of economic weakness, including inflation or political instability;
- burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

## RISK FACTORS

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

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

Our financial statements set forth in Appendix I to this Document are presented in RMB. Certain of our expenses and most of the proceeds from loans from shareholders and/or related parties and equity financing of our Company are denominated in RMB while certain inter-company balances of the Company and certain bank balances and cash of the Group are denominated in U.S. dollars. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates.

The value of the RMB against the Hong Kong dollars, the U.S. dollars, Euro and other currencies fluctuates, is subject to changes resulting from the PRC government’s policies and depends to a large extent on domestic and international economic and political developments as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between the RMB and the Hong Kong dollars, the U.S. dollars, Euro or other currencies in the future. In addition, the PBOC regularly intervenes in the foreign exchange market to limit fluctuations in RMB exchange rates and achieve policy goals. 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 RMB against USD, Hong Kong dollars or other foreign currencies.

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

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## RISK FACTORS

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*Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and may, as a result, negatively affect our business, financial condition and results of operations.*

Our reputation and customer perception of our brand are critical to our business. Maintaining and enhancing our reputation and recognition depend primarily on the quality and consistency of our product candidates. If we are unable to maintain and further enhance our reputation and recognition, our ability to attract and retain customers may be impeded and our business prospects may be materially adversely affected. Any negative publicity concerning us, our affiliates or any entity that shares the “Cali Biosciences” name, our Shareholders, Directors, officers, employees and business partners, management, even if untrue, could adversely affect our reputation and business prospects. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees and business partners were in compliance with any laws or regulations or became involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity. We cannot assure you that negative publicities about us or any of our affiliates or any entity that shares the “Cali Biosciences” name would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition. In addition, referrals and word of mouth have significantly contributed to our ability to establishing new partnerships. As a result, any negative publicity about us could adversely affect our ability to maintain our existing collaboration arrangements or attract new collaboration partners, and we may not be able to diffuse such negative publicity to the satisfaction of our investors and customers.

*There exist risks relating to the inconsistency between the designated land use and the actual land use of our leased property in Shenzhen and our failure to complete the property leasing registration for our leased property in Shanghai.*

As of the Latest Practicable Date, we lease an area of 1,227.53 sq.m. in Shenzhen (the “**Shenzhen Leased Property**”) as laboratory and office. The actual land use of the Shenzhen Leased Property is not exactly consistent with its approved land use as specified in its title certificate. If the owner of this property is required by competent authorities to rectify such land use, we may have to relocate and bear relocation costs and other additional expenses. If any relocation is required, we believe that we will find alternative legal premises in the relevant regions. However, we may not be able to find other suitable property to be leased as our laboratory and office in a timely manner which may affect our future business operations. As of the Latest Practicable Date, we have not received any notice from the owner that the competent authorities will take rectification measures with respect to the Shenzhen Leased Property.



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## RISK FACTORS

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As of the Latest Practicable Date, the lease agreement with respect to our leased property in Shanghai currently used as an office had not been registered and filed with the relevant regulatory authority, because the property owner refused to perform necessary procedures for lease registration. With respect to the unregistered lease, our PRC Legal Advisor is of the view that the non-registration of the lease agreement will not affect the validity of such lease agreement but the relevant local housing administrative authority can require us to complete the registration within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 for the delay in making the registration. During the Track Record Period and as of the Latest Practicable Date, we had not received any such request or suffered any such fine from the competent authorities. For more details, see “Business – Land and Properties.”

***Failure to comply with the PRC regulations regarding mandatory social insurance and housing provident fund contributions may subject us to penalties.***

Pursuant to the PRC 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 shall be required to contribute for each of our employees under such plan should be calculated based on the employee’s actual salary level of the previous year, and be subject to a minimum and maximum level as from time to time prescribed by local authorities. During the Track Record Period, we did not pay social insurance and housing provident fund in full for our employees. As a result, in respect of outstanding social insurance contributions, the competent authorities may demand us to pay within a stipulated deadline and we may be liable to a late payment fee; if we fail to make such payments, we may be liable to penalties. In respect of the outstanding housing provident fund contributions, we may be demanded by the competent authorities to pay within a prescribed time limit. Otherwise, further application will be made to the People’s Court for compulsory enforcement. As of the Latest Practicable Date, no competent authorities had imposed administrative action, fine or penalty to us nor had any competent authorities required us to settle the outstanding amount of social insurance payments and housing provident fund contributions. According to our PRC Legal Advisor, the risk that we will be imposed on penalties by competent authorities for the aforementioned matters is low and will not constitute a material adverse effect on our business, financial condition or results of operations. However, we cannot assure you that the competent authorities will hold the same view with us.

***Our Controlling Shareholders have substantial control over the Company and their interests may not be aligned with the interests of the other Shareholders.***

Immediately following the completion of the [REDACTED] (assuming (i) the [REDACTED] becomes unconditional and the [REDACTED] are issued pursuant to the [REDACTED]; (ii) the [REDACTED] is not exercised; and (iii) Bangzhao’s Acquisitions have been completed), our Controlling Shareholders will be entitled to exercise voting rights of [REDACTED] of the Shares of our Company. Subject to the Articles of Association, the Companies Ordinance and the Cayman Companies Act, the Controlling Shareholders will be

## RISK FACTORS

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able to exercise significant control and exert significant influence over our business or otherwise on matters of significance to us and other Shareholders by voting at the general meeting of the Shareholders and at Board meetings. The interest of the Controlling Shareholders may differ from the interests of other Shareholders and they are free to exercise their votes according to their interests. To the extent that the interests of the Controlling Shareholders conflict with the interests of other Shareholders, the interests of other Shareholders can be disadvantaged and harmed.

### RISKS RELATING TO OUR DOING BUSINESS IN CHINA

***The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our product candidates.***

We have substantial operations in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical 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 product candidates in China and reduce the benefits we believe are available to us from developing and manufacturing our product candidates in China. The Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China, which would have a material adverse effect on our business, financial condition and results of operations.

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

Due to our substantial operations in China, our business, results of operations, financial condition 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.

The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased

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## RISK FACTORS

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economic activity in China, which may adversely affect our business and results of operation. 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.

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

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

The PRC Foreign Investment Law (《中華人民共和國外商投資法》) (the “Foreign Investment Law”) came into effect on January 1, 2020. The Foreign Investment Law may materially impact our current corporate governance practices and business operations in many aspects and may increase our compliance costs. For instance, the Foreign Investment Law imposes stringent ad hoc and periodic information reporting requirements on foreign investors and the applicable foreign invested entities. Depending on the seriousness of the circumstances, non-compliance with the information reporting obligations, concealment of information or providing misleading or false information could result in monetary fines or other penalties. In addition, the Foreign Investment Law embodies a PRC regulation trend of rationalizing the foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments.

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

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## RISK FACTORS

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

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

Certain of our operating subsidiaries are incorporated in China. Certain of our Directors and senior management reside in China from time to time. A large portion of our assets are located in China. It may not be possible for investors to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions. On July 14, 2006, Hong Kong and China 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 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》) (“**Arrangement**”), pursuant to which a party with an enforceable final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with an enforceable final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a Chinese court is expressly designated as the court having sole jurisdiction for the dispute.

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》) (“**New Arrangement**”), which seeks to establish a mechanism with further clarification on and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong Special Administrative Region and the China. 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 the Hong Kong Special Administrative Region. The New Arrangement will, upon its effectiveness, supersede the

## RISK FACTORS

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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 China if the parties in the dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against our assets or management in China in order to seek recognition and enforcement of foreign judgments in China.

Furthermore, China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the United States, the United Kingdom, or most other western countries. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

***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》), or 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, where scientific data involving state secrets needs to be provided to foreign parties during the relevant foreign contacts and cooperation, corporate entities shall provide the type, scope and usage of the scientific data, and submit the information to the competent authorities for approval according to the specified procedures for confidentiality management. Upon approval by the competent authorities, corporate entities shall undergo the required procedures, and enter into the confidentiality agreements with the users of the scientific data. 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. If and to the extent our R&D of product candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical 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 product candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions 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.

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## RISK FACTORS

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

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund.

In response to the persistent capital outflow in China and RMB’s depreciation against the U.S. dollar, People’s Bank of China (“PBOC”), and the State Administration of Foreign Exchange (“SAFE”), promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

***Our dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than that which we currently anticipate.***

The Enterprise Income Tax Law of the PRC, or the “EIT Law” (《企業所得稅法》), and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement.



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## RISK FACTORS

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Pursuant to the Arrangement Between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income, or the “Hong Kong Tax Treaty” (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of the PRC-sourced income, and our Hong Kong subsidiary directly holds 25% or more interests in our PRC subsidiary. On February 3, 2018, the STA, issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (《關於稅收協定中“受益所有人”有關問題的公告》), also known as Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner. There is no assurance that the reduced withholding tax rate will be available.

***Restrictions on currency exchange may limit our ability to utilize our revenue effectively in the future.***

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations in the future. The RMB is currently convertible under the “current account”, which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account”, which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries. Hence, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions”, including payment of dividends to us, if applicable, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC government authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. If any portion of our revenue is denominated in RMB, any restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC government authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

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## RISK FACTORS

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***We are subject to PRC tax laws and regulations.***

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past we had acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and had established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. Such adjustments or changes, together with any uncertainty resulting therefrom, could have an adverse effect on our business, financial condition and results of operations.

***Any failure by the Shareholders or beneficial owners of our Shares who are PRC residents to comply with PRC foreign exchange or other regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us or our PRC resident beneficial owners to liability under PRC laws.***

The SAFE has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities, including Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents’ Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (i) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (ii) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive; where a crime is constituted, the criminal liabilities shall be imposed in accordance with the law.

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## RISK FACTORS

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According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (《國家外匯管理局關於發佈〈境內機構境外直接投資外匯管理規定〉的通知》), or SAFE Circular 30, and other regulations, if our Shareholders who are PRC entities do not complete their registration with the competent branches of the SAFE, the NDRC, or the MOFCOM, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our Shareholders may be required to suspend or stop the investment and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restriction.

On February 13, 2015, the SAFE promulgated the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), or SAFE Circular 13, which came into effect on June 1, 2015, pursuant to which local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of the SAFE.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant SAFE rules and other regulations; however, due to the inherent uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not be always practically available in all circumstances as prescribed in those regulations. In addition, we may not always be fully aware or informed of the identities of our beneficiaries who are PRC nationals or entities, and may not be able to compel them to comply with SAFE Circular 37, SAFE Circular 30 or other regulations. We cannot assure you that all of our Shareholders or beneficiaries will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by SAFE rules or other regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise. Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

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## RISK FACTORS

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*We face uncertainty relating to PRC laws and regulations relating to transfers by a non-resident enterprise of assets of a PRC resident enterprise.*

On February 3, 2015, the STA issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》), or Circular 7, as latest amended on December 29, 2017, which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax for the Transfer of Equities by Non-Resident Enterprises (《關於加強非居民企業股權轉讓企業所得稅管理的通知》), or Circular 698, which was previously issued by the STA on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or “PRC Taxable Assets.”

For example, Circular 7 specifies that when a non-resident enterprise transfers PRC Taxable Assets indirectly by disposing of equity interests in an overseas holding company which directly or indirectly holds such PRC Taxable Assets, the PRC tax authorities are entitled to reclassify the nature of an indirect transfer of PRC Taxable Assets by disregarding the existence of such overseas holding company and considering the transaction to be a direct transfer of PRC Taxable Assets, if such transfer is deemed to have been conducted for the purposes of avoiding PRC enterprise income taxes and without any other reasonable commercial purpose.

Except as provided in Circular 7, transfers of PRC Taxable Assets under the following circumstances shall be automatically deemed as having no reasonable commercial purpose, and are subject to PRC enterprise income tax: (i) more than 75% of the value of the equity interest of the overseas enterprise is directly or indirectly attributable to the PRC Taxable Assets; (ii) more than 90% of the total assets (cash excluded) of the overseas enterprise are directly or indirectly composed of investment in China at any time during the year prior to the indirect transfer of PRC Taxable Assets, or more than 90% of the income of the overseas enterprise is directly or indirectly from China during the year prior to the indirect transfer of PRC Taxable Assets; (iii) the overseas enterprise and its subsidiaries directly or indirectly hold PRC Taxable Assets and have registered with the relevant authorities in the host countries (regions) in order to meet the local legal requirements in relation to organization forms, yet prove to be inadequate in their ability to perform their intended functions and withstand risks as their alleged organization forms suggest; or (iv) the income tax from the indirect transfer of PRC Taxable Assets payable abroad is lower than the income tax in China that may be imposed on the direct transfer of such PRC Taxable Assets.

Circular 7 contains certain exemptions, including (i) the Public Market Safe Harbor described below; and (ii) where there is an indirect transfer of PRC Taxable Assets, but if the non-resident enterprise had directly held and disposed of such PRC Taxable Assets, the income from the transfer would have been exempted from enterprise income tax in the PRC under an applicable tax treaty or arrangement. However, it remains unclear whether any exemptions

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## RISK FACTORS

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under Circular 7 will be applicable to the transfer of our Shares that do not qualify for the Public Market Safe Harbor or to any future acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will reclassify such transactions by applying Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares that do not qualify for the Public Market Safe Harbor by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities.

Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore [REDACTED] company in a [REDACTED]”, or the “Public Market Safe Harbor”, which is not determined by whether the parties, number and price of the shares acquired and disposed are previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other [REDACTED] would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in the section headed “Information about this Document and the [REDACTED] – Professional Tax Advice Recommended” in this Document, potential [REDACTED] should consult their professional advisors if they are in any doubt as to the tax implications of [REDACTED], purchasing, holding, disposing of and [REDACTED] in the Shares.

***Under China’s Enterprise Income Tax Law, we may be classified as a “resident enterprise” of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders.***

Under the EIT Law, an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise”, meaning that it can be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. On April 22, 2009, the STA released the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》), or Circular 82, as amended on December 29, 2017, which provides the standards used to classify resident enterprises clarified that dividends and other distributions paid by such resident enterprises which are considered to be PRC source income will be subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting and properties” of the enterprise. In addition, Circular 82 specifies that certain China-invested enterprises controlled by Chinese enterprises or Chinese group enterprises will be classified as resident enterprises if the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and



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## RISK FACTORS

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management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. On July 27, 2011, the STA issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資控股居民企業所得稅管理辦法(試行)》), or Bulletin 45, which became effective on September 1, 2011, as latest amended on June 15, 2018, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Currently, most of the members of our management team are located in China. However, Circular 82 and Bulletin 45 only apply to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreign corporations like us. In the absence of detailed implementing regulations or other guidance determining that offshore companies controlled by PRC individuals or foreign corporations like us are PRC resident enterprises, we do not currently consider our Company or any of our overseas subsidiaries to be a PRC resident enterprise.

Despite the foregoing, the STA may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by a PRC enterprise or enterprise group like us. Finally, under the EIT Law and its implementing rules issued by PRC tax authorities, dividends paid by us to our non-PRC shareholders may be subject to a withholding tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders, and gains recognized by our non-PRC shareholders may be subject to PRC tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders. Any PRC tax liability on dividends or gain described above may be reduced under applicable tax treaties. However, it is unclear whether, if our Cayman Islands holding company is



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## RISK FACTORS

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considered a PRC resident enterprise, non-PRC shareholders might be able to claim the benefit of income tax treaties entered into between PRC and their countries. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

***Government control of currency conversion of and regulations on loans to, and direct investment in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional contributions to our PRC subsidiaries, which could restrict our ability to utilize the [REDACTED] from the [REDACTED] effectively and affect our ability to fund and expand our business.***

The PRC government imposes controls on the convertibility of foreign currencies into RMB. Under China’s existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, PRC government authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with the SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with or approved by certain government authorities, including the MOFCOM or its local counterparts.

In August 2008, the SAFE promulgated the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign Invested Enterprises (《國家外匯管理局綜合司關於完善外商投資企業外匯資本金支付結匯管理有關業務操作問題的通知》), or SAFE Circular 142, providing that the RMB capital converted from foreign-currency-registered capital of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within the PRC. On March 30, 2015, the SAFE released the Notice on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or SAFE Circular 19, which came into force and superseded SAFE Circular 142 from June 1, 2015. On June 9, 2016, the SAFE further promulgated the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (《關於改革和規範資本項目結匯管理政策的通知》), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises, and some foreign exchange restrictions under SAFE Circular 142 are expected to be lifted. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 and SAFE Circular 16 also reiterate that the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. Considering that SAFE Circular 19 and SAFE Circular 16 are relatively new, it is unclear how they will be implemented, and there exist high uncertainties with respect to its interpretation and implementation by applicable government authorities. For example, under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign-currency-registered

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## RISK FACTORS

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capital of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment except for principal-guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using RMB converted from its registered capital to provide loans to a its non-affiliated company.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into RMB. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

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

*No [REDACTED] currently exists for our Shares; an active [REDACTED] market for our Shares may not develop and the market price for our Shares may decline or become volatile.*

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

*The approval, filing and/or other requirements of the CSRC or other PRC governmental authorities may be required in connection with the [REDACTED] under PRC rules, regulations or policies.*

On February 17, 2023, the CSRC released the Trial Administrative Measures on the Overseas Securities Offering and Listing of Domestic Enterprises (《境內企業境外發行證券和上市管理試行辦法》) (the “Overseas Listing Trial Measures”) and five guidelines, which took effect on March 31, 2023. Pursuant to the Overseas Listing Trial Measures, domestic companies that seek to [REDACTED] securities in overseas markets, both directly and indirectly, should fulfill the filing procedure and report relevant information to the CSRC. If a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

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## RISK FACTORS

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As advised by our PRC Legal Advisor, we are required to submit the filing materials to the CSRC within three business days after our application for the [REDACTED] is submitted. However, since the Overseas Listing Trial Measures were newly promulgated, the interpretation, application and enforcement of the Overseas Listing Trial Measures remain largely uncertain. Therefore, we may fail to obtain such filing or meet such requirements in a timely manner or at all, or completion could be rescinded. Any failure to obtain or delay in obtaining such filing or completing such procedures for this [REDACTED], or a rescission of any such filing obtained by us, would subject us to sanctions by the CSRC or other PRC regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operating privileges in China, delay or restrict the repatriation of [REDACTED] or future capital raising activities into China, or take other actions that could materially and adversely affect our business, financial condition, results of operations and prospects, as well as the [REDACTED] of our Shares.

The CSRC or other PRC regulatory authorities may also take actions requiring us, or making it advisable for us, to halt the [REDACTED] or future capital raising activities before settlement and delivery of the Shares offered hereby. Consequently, if you engage in [REDACTED] or other activities in anticipation of and prior to settlement and delivery, you do so at the risk that settlement and delivery may not occur. In addition, if the CSRC or other regulatory authorities later promulgate new rules or explanations requiring that we obtain their approvals or accomplish the required filing or other regulatory procedures for the [REDACTED] or future capital raising activities, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Any uncertainties or negative publicity regarding such approval, filing or other requirements could materially and adversely affect our business, prospects, financial condition, reputation, and the [REDACTED] of the Shares.

***The price and [REDACTED] of our Shares may be volatile, which could lead to substantial losses to investors.***

The price and [REDACTED] of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and [REDACTED] of our Shares. In addition to market and industry factors, the price and [REDACTED] of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting our industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies [REDACTED] on the Hong Kong Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and our Shares may be subject to changes in price not directly related to our performance.

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## RISK FACTORS

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*There will be a gap of several days between pricing and [REDACTED] of our Shares, and the price of our Shares when [REDACTED] begins could be lower than the [REDACTED].*

The initial price to the public of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Hong Kong Stock Exchange until they are delivered, which is expected to be not more than five Business Days after the [REDACTED]. As a result, investors may not be able to [REDACTED] in the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the price of the 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 [REDACTED] begins.

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

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in pro forma net tangible asset value. In order to expand our business, we may consider [REDACTED] additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time.

*Future sales or perceived sales of our Shares in the [REDACTED] by major Shareholders following the [REDACTED] could materially and adversely affect the price of our Shares.*

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

*We cannot assure you that the Shares will remain [REDACTED] on the Stock Exchange.*

Although it is currently intended that the Shares will remain [REDACTED] on the Stock Exchange, there is no guarantee of the continued [REDACTED] of the Shares. Among other factors, the Company may not continue to satisfy the [REDACTED] requirements of the Stock Exchange. Holders of Shares would not be able to sell their Shares through [REDACTED] on the Stock Exchange if the Shares were no longer [REDACTED] on the Stock Exchange.

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## RISK FACTORS

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

Our corporate affairs are governed by our Memorandum and Articles and by the Cayman Companies Act and common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, actions by minority Shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See “Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law” to this Document.

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Controlling Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

*Since we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our Shares for a return on your investment.*

We intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline product candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board declares and pays dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your investment in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares.

## RISK FACTORS

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*Facts, forecasts and statistics in this Document relating to the PRC economy and biotechnology industry may not be fully reliable.*

Facts, forecasts and statistics in this Document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this Document relating to the pharmaceutical industry in and outside China may be inaccurate and you should not place undue reliance on them. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

*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].*

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



## RISK FACTORS

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You should rely solely upon the information contained in this Document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your investment decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective investors should not rely on any such information, reports or publications in making their decisions as to whether to invest in our [REDACTED]. By applying to purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this Document and the [REDACTED].