

RISK FACTORS

An [REDACTED] 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 [REDACTED] 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 and adverse effect on our business, financial condition and results of operations. In any such case, the market price of our Shares could decline, and you may lose all or part of your [REDACTED]. 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” of this document.

In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours. Your [REDACTED] decision should be made in light of these considerations.

RISKS RELATING TO THE DEVELOPMENT AND CLINICAL TRIALS OF OUR DRUG CANDIDATES

Our business and financial prospects depend substantially on the successful development, approval, and commercialization of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approval, and commercialize our drug candidates, including our Core Product, or experience delays in doing so, our business prospects could be adversely affected.

As of the Latest Practicable Date, none of our drug candidates had been approved for commercialization. We recorded losses of RMB3.4 million and RMB207.4 million in 2024 and 2025, respectively. Our future revenue and profitability will substantially depend on our ability to successfully develop, obtain regulatory approvals for, manufacture, and commercialize our drug candidates. We have invested significant capital in developing our existing drug candidates and expect to continue incurring substantial expenditures for development and commercialization. The success of our drug candidates will depend on several factors, including: successful enrollment and completion of clinical trials and preclinical studies; favorable safety and efficacy data; receipt of regulatory approvals; establishing sufficient manufacturing capabilities; effectively managing clinical trials across multiple jurisdictions; reaching acceptable terms with third-party service providers such as CROs, CDMOs, and trial sites; satisfactory performance by contracted parties in compliance with protocols and applicable laws; obtaining and maintaining intellectual property protection and regulatory exclusivity; avoiding infringement of third parties’ intellectual property rights; successfully launching approved drug candidates; competition with other products; maintaining acceptable safety profiles post-approval; and obtaining sufficient supplies of pharmaceutical products necessary for combination therapy trials. If we fail to achieve these factors in a timely manner, we could experience significant delays or be unable to commercialize our drug candidates, which would materially harm our business and ability to generate sufficient revenues to continue operations. Our drug candidates may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. For related risks, see “— The development process of pharmaceutical products is typically lengthy and costly with uncertain outcomes, and if clinical trials of our drug candidates fail to demonstrate safety and efficacy profiles that satisfy regulatory authorities or do not yield positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.”

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

We face competition for our current and future drug candidates. Our drug candidates may compete with existing inhibitors targeting the same molecular targets and approved for the same indications. Approval of our drug candidates by the NMPA, FDA or other regulatory authorities will not preclude competition from well-established pharmaceutical companies, universities, and research institutions that have commercialized or are developing drugs for the same indications. These competitors may have substantially greater financial, technical, and other resources, including more advanced commercial infrastructure, more drug candidates in late-stage development, and established marketing and manufacturing teams. In addition, our competitors may succeed in developing, acquiring, or licensing products that are more effective or lower cost than our drug candidates, or achieve earlier patent protection, regulatory approvals, and market penetration. To compete successfully with approved products, we must demonstrate compelling advantages in efficacy, convenience, tolerability, or safety to overcome price competition. Furthermore, disruptive technologies and medical breakthroughs may intensify competition and render our drug candidates obsolete or noncompetitive.

The development process of pharmaceutical products is typically lengthy and costly with uncertain outcomes, and if clinical trials of our drug candidates fail to demonstrate safety and efficacy profiles that satisfy regulatory authorities or do not yield positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Clinical development is capital-intensive and may demand years of effort to complete, we may encounter unexpected difficulties while executing our clinical development plans for our drug candidates. The results of planned clinical trials or other future clinical trials could be significantly different and deviate from our expectation, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. Unexpected events during clinical trials could delay or prevent regulatory approval or commercialization. These include: regulators, IRBs, or ethics committees denying authorization to commence or conduct trials at specific sites; manufacturing issues, such as supply quality, GMP compliance, or obtaining sufficient quantities from third parties; negative or inconclusive results requiring additional trials or program abandonment; failure of third-party contractors or investigators to meet regulatory or contractual obligations; and the suspension or termination of trials due to lack of clinical response, unexpected characteristics, or unacceptable health risks to participants. If clinical trials require expansion, fail to complete, or yield negative, modest, or unsafe results, we may face delayed or denied regulatory approval. Consequences include narrower approved indications, post-approval market withdrawal, mandatory additional testing, distribution restrictions, reimbursement failures, or product liability litigation. Furthermore, significant delays could increase development costs, shorten exclusivity periods, or allow competitors to enter the market first, thereby impairing our commercialization efforts and harming our business operations.

The NDA for our Core Product, LP-168 may be granted on a conditional basis, which imposes ongoing post-approval obligations. Failure to fulfill certain conditions could result in the revocation of our NDA approval, which would materially and adversely affect our business.

Our Core Product, LP-168, is currently under NDA review by the NMPA in China. Based on our communications with the CDE and the *Technical Guidelines for the Applicability of Single-Arm Clinical Trials to Support Marketing Applications for Antineoplastic Drugs* (單臂臨床試驗用於支持抗腫瘤藥上市申請的適用性技術指導原則) issued by the CDE in March 2023 (the “**March 2023 Technical Guidelines**”), we anticipate that any approval granted for LP-168 will be a conditional approval. We expect the CDE to require us to conduct a confirmatory study (the “**Additional Registrational Clinical Trial**”), which may take the form of: (i) a double-blinded, randomized, and

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controlled registrational clinical trial; or (ii) a single-arm clinical trial involving a larger subject population with a longer follow-up period. Pursuant to the March 2023 Technical Guidelines, we are required to initiate this Additional Registrational Clinical Trial prior to the granting of the conditional NDA. Conditional approval, if obtained, it is subject to revocation. We must successfully complete the Additional Registrational Clinical Trial, which was initiated in January 2026 and demonstrate favorable safety and efficacy profiles to convert the conditional approval into a full approval. If the Additional Registrational Clinical Trial fails to meet its primary endpoints, demonstrates an unfavorable benefit-risk profile, or if we fail to complete the trial within the timeframe specified by the regulatory authorities, the NMPA may revoke our conditional NDA approval. Such an event would have a material and adverse effect on our business, financial condition, results of operations, and prospects. Further, the potential clinical advantages of LP-168 remain to be definitively demonstrated and validated through the results of our ongoing and future clinical trials, and we cannot guarantee that these studies will yield favorable or conclusive data. Even if LP-168 successfully completes clinical development and obtains all necessary regulatory approvals, its ultimate commercial success is not guaranteed and will depend heavily on a variety of post-approval factors. These factors include, but are not limited to, successful pricing negotiations, securing adequate insurance coverage and reimbursement, and the effective execution of our marketing and commercialization efforts. If we are unable to clearly demonstrate the clinical benefits of LP-168 to physicians and patients, or if we fail to achieve favorable pricing and broad market acceptance against competing therapies, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

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

We may experience difficulties in participant enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the clinical trial protocol, the resources we have to facilitate timely subject enrollment in our clinical trials, the efforts made by trial execution personnel to screen and recruit eligible subjects, the ability to obtain and maintain informed consents, epidemics, and the proximity and availability of clinical trial sites for prospective subjects, among others. In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates. Such competition will likely reduce the number and types of patients available to us. Delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent the completion of these trials and adversely affect our ability to advance the development of our drug candidates.

AEs or undesirable side effects caused, or are perceived to be caused, by our drug candidates could interrupt 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.

AEs and side effects could compel us or regulators (e.g. FDA and NMPA) to halt our clinical trials, resulting in narrowed indications, restrictive labeling, protocol changes, or the delay or denial of approval. If trials reveal unacceptable AE severity or prevalence, regulators may mandate the suspension of studies or cessation of development for some or all indications. Furthermore, AEs could impede subject recruitment and retention or trigger liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects. If we or our partners identify undesirable side effects in our drugs after approval, significant negative consequences may follow. Regulatory authorities could withdraw approvals, revoke licenses, or require marketing suspensions. Further, combination therapy using our drug candidates together with third-party agents may involve AEs, which in some cases could be exacerbated compared with AEs from monotherapies. Any of these events could prevent us or our collaboration partners, as applicable, from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, financial condition, results of operations and prospects.

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Our pre-clinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these drug candidates on a timely basis or at all.

Many of our drug candidates are still in the pre-clinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the NMPA, FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for the contemplated clinical development of our preclinical drug candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND applications or similar applications will result in the NMPA, FDA or other regulatory authorities allowing clinical trials to begin.

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

We cannot guarantee that we will be successful in discovering and developing potential drug candidates. Additionally, there can be no assurance that our collaboration with third parties will deliver the expected results. We may focus our efforts and resources on potential programs or drug candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization for a number of reasons, including, without limitation, the following: the research methodology used may not be successful in identifying potential indications and/or new drug candidates; potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired efficacy; it may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio; or predicting clinical performance can be challenging. Accordingly, there can be no assurance that we will be able to discover and develop new drug candidates or identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially and adversely affect our future growth and prospects.

RISKS RELATING TO OUR FINANCIAL POSITION

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

We are a pharmaceutical company with a limited operating history. To date, our drug candidates are in pre-commercialization stages, with profitability expected to follow successful product launches aligned with our strategic commercialization roadmap. Our limited operating history may make it difficult to evaluate our prospects for future performance. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business may suffer and you may lose all of your [REDACTED] in us.

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We may not achieve successful outcomes from our substantial investments in research and development and may fail to capitalize on more promising opportunities due to resource allocation decisions.

In 2024 and 2025, our research and development expenses were RMB149.5 million and RMB128.7 million, respectively. We may not be able to successfully develop or commercialize new technologies or drug candidates in a timely or cost-effective manner, or obtain adequate intellectual property protection. In addition, as we have limited financial and managerial resources, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities, and we may be required to recognize impairment losses on related intangible assets or face other negative consequences which could adversely affect our financial condition and results of operations. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration or license arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration or license arrangement, which could materially adversely affect our future growth and prospects.

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

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees. Increasing market competition may cause market demand and competition for qualified employees to intensify. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially and adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused by labor disputes.

We have incurred significant operating losses during the Track Record Period, and we anticipate that we will continue to incur significant R&D expenses and may fail to achieve or maintain profitability in the future.

Investment in the development of innovative biopharmaceutical products can be highly speculative. We incurred losses of RMB3.4 million and RMB207.4 million in 2024 and 2025, respectively. Substantially all of our operating losses during the Track Record Period resulted from our research and development activities, which exceeded the income and gains we recognized in the same periods. We expect to continue to incur losses in the near future and that the loss may increase as we continue to carry out certain activities relating to our development, including but not limited to the following: continue to advance the clinical trials and preclinical studies of our drug candidates; seek regulatory approvals for our drug candidates and commence commercialization; identify additional drug candidates with significant market potential; respond to scientific advancements, new technologies and market developments; maintain, protect and expand our intellectual property portfolio; and enter into additional strategic collaborations to maximize the value of our drug candidates. We may not be able to sustain profitability in subsequent periods.

We had incurred net operating cash outflow during the Track Record Period and there can be no assurance that we will not have net operating cash outflow in the future.

We recorded net operating cash outflow of RMB113.4 million and RMB124.8 million in 2024 and 2025, respectively. For details, please refer to the paragraph headed “Financial Information — Liquidity and Capital Resources — Cash Flows.” We cannot assure you that we will be able to generate positive cash flow from our operations in the future. If we encounter net operating cash outflow in the future, we may not have sufficient working capital to cover our operations, and our business, results of operations, financial conditions and business prospects may be materially and adversely affected.

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

We have historically received various financial incentives, which primarily representing subsidies received from the local governments for the purpose of compensation of expenses spent on research and clinical trial activities, and allowances for new drug development. We recorded government grants of RMB6.9 million and RMB10.9 million in 2024 and 2025, respectively. These government grants are provided to us at the discretion of the relevant government authorities, who could determine at any time to eliminate or reduce these financial incentives, and may therefore vary from period to period going forward. For details, see “Financial Information — Description of Selected Components of the Consolidated Statements of Loss or Profit and Other Comprehensive Expenses — Other Income and Gains.” There is no assurance that we will continue to receive such government grants at a similar level in the future, or at all.

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

As of December 31, 2024 and 2025, we had net liabilities of RMB880.7 million and RMB1,067.9 million, respectively. In addition, we recorded net current liabilities of RMB900.6 million and RMB1,088.0 million as of the same date, respectively. A net liabilities position can expose us to liquidity and financial risks. If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We have granted share-based payments to, among others, attract and retain outstanding individuals to serve the Company. We may continue to grant share-based payment to employees in the future. In 2024 and 2025, we incurred share-based payment expenses of RMB22.3 million, and RMB25.2 million, respectively. See Note 29 of the Accountants’ Report set out in Appendix I to this document. As a result, our expenses associated with share-based payment may increase, which may have an adverse effect on our results of operations. We may periodically re-evaluate and adjust vesting schedules, lock-up periods, exercise prices, or other key terms of grants under our existing and future share incentive plans, potentially resulting in substantial changes to our share-based payment charges. In addition, such share-awards may dilute the shareholding percentage of our existing Shareholders and could result in a decline in the value of our Shares.

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

During the Track Record Period, we financed our operations primarily through proceeds from the issuance of preferred shares. We expect to fund our future operations primarily with existing cash and cash equivalents, [REDACTED] from the [REDACTED], future commercialization and sales of our drug candidates, equity offerings, out-license and collaboration arrangements, proceeds from commercial loans, and other sources. Changes in our ability to fund our operations may affect our cash flow and results of operations. We may nevertheless require substantial additional capital to meet our continued operating cash requirements, especially to fund our research and development activities, commercialization of our drug candidates and development of manufacturing capabilities. As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all.

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

To enhance our growth, we may pursue acquisitions or strategic partnerships, which entail numerous risks. These include substantial negotiation costs, increased operating expenses, assumption of debt, and shareholder dilution. We face challenges in integrating operations and IP, distracting management, retaining key personnel, and managing counterparty risks. We may fail to generate expected revenue or discover post-acquisition deficiencies in internal controls, compliance, or product quality that lead to liability. Furthermore, integration difficulties, unexpected penalties, large one-time expenses, or future amortization costs could materially harm our reputation, business, and financial condition.

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We rely on third parties to ensure a stable and sufficient supply of quality materials for our drug development. Any disruptions or significant price increases in this supply could negatively impact our business.

During the Track Record Period, we relied on third parties to supply certain APIs and other R&D materials for our R&D practice. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our drug candidates. Any disruption in production or the inability of our suppliers to provide adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates. Moreover, there is no assurance that current suppliers have the capacity to meet our demand in the future. We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In addition, we cannot assure you that we will be able to identify and rectify all quality issues. We cannot assure you that these third-party suppliers will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. The non-compliance of these third parties may also subject us to potential product liability claims, result in our failure to comply with the continuing regulatory requirements.

We rely on third parties to manufacture our drug candidates for clinical development and may engage with third parties for commercialization. If these third parties fail to duly perform their contractual obligations, meet expected timelines or maintain necessary regulatory licenses, our business, financial condition and results of operations could be materially and adversely affected.

We have worked with and may continue to work with third-party service providers on our ongoing preclinical and clinical programs. If we or any of our CROs or clinical investigators fail to comply with the applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our registrational clinical trials must be conducted with products produced under GMP regulations. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Furthermore, due to the involvement of third parties such as CROs, the data we gather in our research and development may be affected by factors unrelated to our drug candidates or out of our control, which could adversely affect the reliability of results derived from our research and development activities. If our business partners fail to obtain and maintain necessary permits, licenses and certificates in their operations, our ability to conduct our business could be materially impaired. Any changes in the standards used by governmental authorities in considering whether to renew or reassess our business partners' licenses, permits and certifications, as well as enactment of any new regulations that may restrict the operation of our business partners' operations, which could materially and adversely affect our business, financial condition and results of operations. If relationships with third-party collaborators terminate, we may not find alternative arrangements on commercially reasonable terms. We cannot control whether collaborators devote

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sufficient time and resources to our programs, and switching collaborators involves additional cost and delays affecting development timelines. If collaborators fail to complete studies, maintain necessary licenses, or adequately perform their obligations, it could delay regulatory approvals. Breach or termination of collaborator agreements may prevent successful commercialization, materially affecting our business, financial condition, and results of operations.

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

Our relationships with principal investigators, physicians and other industry experts play an important role in our research and development and marketing activities. We cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, or choose to no longer cooperate with us or cooperate with our competitors instead. If we are unable to develop and maintain our relationships with industry participants as anticipated, our business, financial condition and results of operations may be materially and adversely affected.

RISKS RELATING TO COMMERCIALIZATION AND MANUFACTURING OF OUR DRUG CANDIDATES

We do not have experience in launching and marketing drug candidates and may not be able to successfully do so in the future.

We have not yet demonstrated an ability to launch and commercialize drug candidates. We may require a longer time frame or be less cost-efficient in the commercialization process than a company with more experience launching and marketing drug candidates. Furthermore, if we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates, we will likely pursue collaborative arrangements regarding the sales and marketing of our drug candidates. If we choose to pursue this path, we may have little or no control over the marketing and sales efforts of such third parties beyond contractual terms. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel and any revenue we receive will depend upon the efforts of such third parties. As a result, we may not be able to generate the anticipated product sales revenue.

The size of the actual markets for our drug candidates may be smaller than our estimates and our drug candidates may not be able to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the biopharmaceutical industry that would be necessary for their commercial success.

Our projections of the number of patients who have the potential to benefit from treatment with our drug candidates are based on our beliefs and estimates. The actual addressable market may be smaller than anticipated. Additionally, our candidates may fail to gain market acceptance if physicians, patients, or payers prefer alternatives. Commercial success depends on factors including: approved indications; efficacy, safety, and side effect profiles; perceived advantages over competitors; labeling restrictions; timing of market entry; cost-effectiveness and reimbursement availability; pricing pressures; ease of administration; and sales effectiveness. In addition, there is no guarantee that any of our drug candidates, even if approved, would be approved for the line of therapy we are ultimately aiming for. Even if our approved drug candidates achieve market acceptance, such market acceptance may not be maintained over time if new drug candidates or technologies are introduced that are more favorably perceived than our drug candidates, have better safety and efficacy profiles or render our drug candidates obsolete.

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If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

We currently do not have any drug candidates that have gained regulatory approval for sale in the PRC, the United States or any other country, and we cannot guarantee that we will ever have marketable internally developed drugs. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approval in certain jurisdiction could require additional nonclinical studies or clinical trials, which could be costly and time consuming. For all of these reasons, we may not obtain regulatory approvals on a timely basis, if at all. The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the PRC and the United States, and approval is never guaranteed. Following any approval for commercial sale of our drug candidates, certain changes to the drug may be subject to additional review and approval by the NMPA, the FDA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

The commercialization of our drug candidates, if approved, may be subject to 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 new therapeutic products vary widely from jurisdiction to jurisdiction. The ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Reimbursement availability and levels for commercialized drug products are uncertain and may impact demand or pricing. There may be significant delays in obtaining reimbursement, and coverage may be more limited than approved indications. In the United States, no uniform coverage and reimbursement policy exists among third-party payers, requiring time-consuming and costly payer-by-payer negotiations with no assurance of adequate coverage. Moreover, reimbursement eligibility does not guarantee full cost coverage (including R&D, manufacturing, sales, and distribution) in all cases or at adequate rates; interim payments for new drugs may prove insufficient or temporary, vary by use/clinical setting, reference lower-cost drugs, or integrate into existing service payments, while mandatory discounts/rebates from government/private payers — or future import liberalization — could further reduce net prices, materially adversely affecting our business, results of operations, and financial condition if profitable coverage is not promptly obtained.

If our products fail to be timely included in, or are removed or excluded from, national, provincial or other government-sponsored medical insurance programs, our revenue and financial performance could be adversely affected. Insurance coverage is a critical factor in a patient’s ability to afford treatments.

If a pharmaceutical product is covered by medical insurance, whether provided by the government or a commercial insurer, patients may receive reimbursement for all or a portion of the cost. Any delay in inclusion of our products in the NRDL or other government-sponsored medical insurance programs may adversely affect their market adoption and sales growth. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from the sales of marketed products would be highly dependent on patient self-payment, which can make our products less attractive. Patients may choose other products with similar efficacy but lower price which have been included in the NRDL. There can

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be no assurance that any of our products currently listed in these medical insurance catalogs will remain listed, or that changes in the scope of reimbursement will not negatively affect our products. If any of our products or their indications are removed from any medical insurance catalog, or if the scope of reimbursement is reduced, demand for our products may decrease and our revenue and financial performance could be adversely affected. Government authorities may accept our application for the inclusion of products in the catalog. Our potential revenue from the sales of these products could still decline over time, as we may be required to significantly lower their prices to secure such inclusion. For details, please see “Business — Pricing.”

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

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ drugs and drug candidates. Currently, there are not any unfavorable guidelines, recommendations and studies published by various organizations in relation to our drug candidates. However, any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to competing drug products, could result in current or potential decreased use and/or sales of, and revenue from one or more of our drug candidates. Furthermore, our success depends in part on the ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third parties’ guidelines, recommendations or studies.

We may not be able to maintain effective quality control and quality assurance over our drug candidates.

During the Track Record Period, we primarily procured third-party manufacturing services to manufacture drug candidates for clinical development. For risks associated with third-party manufacturing, see “— Risks Relating to Dependence on Third Parties — We rely on third parties to manufacture our drug candidates for preclinical and clinical development and may engage with third parties for commercialization. If third-party manufacturers fail to meet contractual, timeline, or licensing obligations, we may be unable to approve or commercialize candidates, materially harming our business.” Product quality relies on effective quality control and assurance (QC/QA) protocols; however, we cannot guarantee these will consistently prevent deviations or that standard operating procedures (SOPs) will remain current. We may fail to detect defects caused by factors often outside our control, such as manufacturing errors, technical malfunctions, human error, malfeasance, tampering, or raw material issues. Deterioration in QC/QA or SOPs could render products unsuitable, create audit gaps, jeopardize future GMP certifications, and damage our reputation and partnerships, materially affecting our financial condition.

Our drug candidates may involve risks of contamination during production.

Production of pharmaceutical products is a complex process, which may be exposed to a contamination during production. In addition, manufacturing operations based on the sharing of equipment and facilities are common, and activities such as developing clinical samples which may increase chances of cross-contamination. Contamination of our future pharmaceutical products, if and when approved and manufactured, could have a material adverse effect on our commercial prospects and financial results. In addition, contaminated products that are unknowingly distributed could result in patient harm, damage the reputation of our drug candidates and company, and expose us to liability claims, regulatory enforcement actions.

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Inability to conduct effective sales and marketing activities would negatively affect the sales volume of our drug candidates after they are approved for commercialization, and our operations, revenue, profitability, and business prospects could be adversely affected.

Successful sales and marketing are crucial to increase the market penetration of our drug candidates after they are commercialized, expand coverage of hospitals and other medical institutions and promote new products in the future. If we or our collaborators are unable to increase or maintain the effectiveness and efficiency of sales and marketing activities, the sales volumes and business prospects could be adversely affected. If we or our commercialization collaborators are unable to effectively train the sales representatives, sales and marketing of our drug candidates may be less successful than desired. Moreover, if we or our collaborators are unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals, sales volume of our products may be adversely affected, and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

If safety, efficacy, or other issues arise with any medical product that is used in combination with or to facilitate the use of our drug candidates, we may be unable to market such drug candidates or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. If the NMPA, the FDA or another comparable regulatory agency revokes or denies its approval of a component therapeutic, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts. In addition, we may fail our commercialization effort because products that facilitate the use of our drug candidates incur safety, efficacy or availability issues. The lack of regulations presents uncertainties to our commercialization efforts and may have an adverse effect on our business and results of operations.

We may explore the licensing of commercialization rights or other forms of collaboration worldwide, which will expose us to additional risks of conducting business in additional international markets.

We intend to focus on China and U.S. markets and may explore out-license and collaboration arrangements with suitable third party partners in these markets. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including: efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates; unexpected changes in tariffs, trade barriers and regulatory requirements; changes in a specific country's or region's political and cultural climate or economic condition; differing regulatory requirements for drug approvals and marketing internationally; difficulty of effective enforcement of contractual provisions in local jurisdictions; potentially reduced protection for intellectual property rights; potential third-party patent rights; economic weakness, including inflation or political instability; compliance with tax, employment and labor laws for employees traveling abroad; the effects of applicable tax structures and potentially adverse tax consequences; currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country; workforce uncertainty and labor unrest; the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a non-U.S. market with low or lower prices rather than buying them locally; production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires. These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

RISK FACTORS

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Our commercial success depends on our ability to protect our proprietary technology by obtaining, maintaining, and enforcing our intellectual property rights. We seek to protect the technology and drug candidates that we consider commercially important primarily by filing patent applications in China and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. See “Business — Intellectual Property” for details. However, our patent applications may not be granted or may not effectively prevent third parties from commercializing competitive technologies. Relevant prior art could invalidate patents, and material defects could render them unenforceable. Even if patents are issued, third parties may challenge their validity or scope, and competitors may develop non-infringing alternatives. Filing, prosecuting, maintaining, and defending patents worldwide could be prohibitively expensive, and intellectual property rights vary in scope and strength across countries. We may not be able to prevent third parties from practicing our inventions or selling infringing products in all jurisdictions, and such products may compete with our drug candidates. The legal systems of some countries do not favor enforcement of patents and other intellectual property, and enforcement proceedings in foreign jurisdictions could result in substantial costs, divert resources, risk patent invalidation or narrow interpretation, and provoke third-party claims against us. Accordingly, our efforts to enforce intellectual property rights worldwide may be inadequate to obtain significant commercial advantage, which could materially and adversely affect our business, financial condition, and prospects.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The CNIPA, the USPTO and other applicable patent authorities require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. There are situations in which such non-compliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. If we or our collaboration partners fail to maintain the patents and patent applications covering our drug candidates or if we or our collaboration partners otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved. In addition, according to the Patent Law of the PRC and related regulations, we and our collaboration partners are required to file the patent license agreements with the CNIPA within three months after the effective date thereof, otherwise we may lose our exclusive right to use our in-licensed patents if the licensor grants a bona fide third party a right to use the patent. Before such filings become effective, we may not be able to protect ourselves against challenges brought by bona fide third parties to whom the licensors may, for any reason, grant a right to use the same patents we have in-licensed.

If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

Patents have limited duration, and upon expiration we will not be able to assert such rights against competitors, which may adversely affect our business. Given the time required for development, testing, and regulatory review, patents protecting our drug candidates might expire before or shortly after commercialization, potentially providing insufficient rights to exclude others from commercializing similar products. Applicable authorities may refuse to grant our applications for patent term extensions or grant more limited extensions than requested due to factors such as failing to exercise due diligence, missing deadlines, or failing to satisfy applicable requirements. If we are unable to obtain extensions or receive shorter terms than requested, competitors may obtain approval of competing products following our patent expiration, harming our business.

RISK FACTORS

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

Our intellectual property rights could be challenged or invalidated. In infringement proceedings, a court may decide that our patents are not valid, unenforceable, or do not cover the technology in question. We may also face infringement claims by third parties relating to our trademarks, trade names, copyrights or other intellectual property rights. Court may also award only monetary damages rather than an injunction in an infringement judgment, which may not be an adequate remedy. Enforcing our rights may also provoke counterclaims that could be costly to defend. An adverse result could put our intellectual property rights at risk of being invalidated or narrowly interpreted, and substantial discovery requirements could compromise confidential information. Public announcements of litigation developments perceived as negative could adversely affect our Share price. Any loss of intellectual property protection could materially impact our drug candidates and business.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

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

We rely on trade secrets, confidential information, and unpatented know-how to maintain our competitive position. When we share trade secrets with third parties for manufacturing, commercialization, or collaboration, the risk of misappropriation or disclosure increases. We cannot guarantee that adequate non-disclosure agreements have been executed with all parties who have accessed our proprietary information. Competitors may discover our trade secrets through breach of agreements, independent development, or publication by collaborators. Enforcing trade secret claims is difficult, expensive, and unpredictable, and if we cannot prevent unauthorized disclosure, we may lose our competitive advantage. Additionally, some employees, consultants, and advisers may have proprietary rights agreements with former employers. We may face claims that we or our personnel have used or disclosed intellectual property belonging to former employers. We may also be unsuccessful in executing assignment agreements with individuals who develop intellectual property we regard as our own, or such agreements may be breached. Litigation to defend or prosecute such claims could be costly and distracting, and if unsuccessful, we may lose valuable intellectual property rights or personnel, materially affecting our business, financial condition, and prospects.

Intellectual property and other laws and regulations are subject to change, and intellectual property rights do not necessarily protect us from all potential threats.

Obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain, and we cannot predict the breadth of claims that may be allowed or enforced. Periodic proposals for changes to patent laws in China, the U.S., and other countries could impact our ability to enforce our proprietary technology. Our patent terms may be eligible for extension, but

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third-party patents may also be extended, potentially affecting our ability to commercialize products without infringement risks. If commercialization is delayed, technological advances and new competitor products may render our products non-competitive. Evolving judicial interpretation and future actions by legislative bodies, courts, or patent offices could change laws and regulations in unpredictable ways that weaken our ability to obtain new patents or enforce existing ones, materially affecting our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations. The following examples are illustrative: others may be able to make drug candidates that are the same as or similar to our drug candidates but that are not covered by the claims of the patents that we own or may have exclusively licensed; others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and we may not develop additional technologies that are patentable.

RISKS RELATING TO GOVERNMENT REGULATIONS

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

All jurisdictions in which we operate regulate the research, development, manufacturing, and commercialization of biopharmaceutical products extensively. We intend to implement a global development strategy focused on China and the United States, and differences in regulatory regimes could increase our compliance burden and costs. We must obtain and maintain certain licenses and permits, and if regulatory authorities determine we are operating without requisite approvals or impose new requirements, they may levy fines, confiscate income, revoke business licenses, or require us to discontinue operations. Failure to comply with applicable requirements during development, approval, or post-approval may result in administrative or judicial sanctions. Any non-compliance with laws, regulations, or industry standards could result in fines, termination of research, disqualification of data, or bans on future sales, materially affecting our reputation, business, and financial condition. Even successfully defending against regulatory actions could cause significant legal expenses, divert management attention, and adversely affect our results.

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

The regulatory approval process is inherently uncertain, and the time required to obtain approvals from the NMPA, FDA, and other regulatory authorities is unpredictable. Regulatory authorities may raise concerns about submissions, request additional data, question study design, or interpret results differently than anticipated. We may fail to receive regulatory approvals for various reasons, including disagreement on clinical trial design, failure to demonstrate safety and efficacy, insufficient clinical data, procedural errors, failure to pass GCP or GMP inspections, or unexpected changes in regulations. Regulatory authorities may also require additional information, approve fewer indications than applied for, or impose post-marketing requirements. Failure to obtain timely regulatory approvals or approvals with intended indications could negatively impact commercial prospects and cause reputational damage. If our drug candidates fail to demonstrate safety and efficacy to regulatory satisfaction, we may not realize any revenue, materially affecting our business, financial condition, and prospects.

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Changes in laws and regulations relating to the biopharmaceutical industry may result in additional compliance risks and costs.

In China, the U.S., and other jurisdictions, ongoing legislative and regulatory changes relating to the biopharmaceutical industry and healthcare system could affect the sales, profitability, and prospects of our drug candidates. These laws and regulations are subject to updates, and their application may evolve as new guidance becomes available, resulting in continuing compliance uncertainty and additional costs for revising our disclosure and governance practices. Failure to comply with these laws and any subsequent changes may subject us to penalties and harm our business.

We are subject to stringent data privacy and cybersecurity laws, regulations and policies, and we may be restricted from transferring data abroad or using human genetic resources collected within the PRC.

The Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), requires enterprises to seek governmental approval before transferring scientific data involving state secrets abroad or to foreign parties. Researchers conducting government-funded research must also submit relevant data for management before publishing in foreign journals. If our R&D data is subject to these measures or subsequent laws, there is no assurance we can always obtain approvals for sending scientific data abroad or to foreign partners in China. The regulatory environment in China imposes stringent requirements on the collection, use, and transfer of human genetic resources and data. Under the HGR Regulation and Biosecurity Law, foreign entities are prohibited from collecting, preserving, or exporting China’s human genetic resources without proper approvals or filings, and any non-compliance may hinder our drug R&D and subject us to penalties. In addition, evolving laws such as the Cybersecurity Law, Data Security Law, and Personal Information Protection Law impose increasing obligations regarding data security, privacy protection, and personal information processing. Further, under the Cybersecurity Review Measures and the Data Security Regulations, our data activities or the use of network products and services may be subject to review or additional administrative procedures. With new and developing rules governing cross-border data transfer, including the Data Export Security Assessment Measures and the Standard Contractual Clauses Measures, future changes and enhanced compliance requirements may increase our operational costs, constrain liquidity, or materially and adversely affect our business and financial performance.

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

We and certain third parties we work with, such as our CROs, CMOs, CDMOs and other business partners, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We 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, hazardous or radioactive materials. We may also incur liabilities due to injuries to our employees resulting from the use of or exposure to hazardous materials, and we do not maintain insurance covering such potential liabilities. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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We may be subject, directly or indirectly, to applicable anti-kickback, false-claim, physician payment transparency, or fraud and abuse laws, or similar healthcare and security laws and regulations in China, the U.S. and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers and physicians play a primary role in recommending and prescribing our products. If we obtain regulatory approval and commercialize our drug candidates in China or the U.S., our operations will be subject to various fraud and abuse laws, including the PRC Anti-Unfair Competition Law, PRC Criminal Law, the Federal Anti-Kickback Statute, the Federal False Claims Act, and physician payment sunshine laws. These laws may impact our sales, marketing, and education programs. We are also subject to patient privacy regulations and state and non-U.S. equivalents of these healthcare laws, some of which are broader in scope and apply to services reimbursed by any source. Some states require compliance with industry codes of conduct and impose marketing restrictions or disclosure requirements. Violations may be punishable by criminal or civil sanctions, and private individuals may bring actions under false claims laws. Law enforcement authorities are increasingly focused on enforcement, and governmental authorities may conclude our business practices do not comply with applicable laws. If actions are instituted against us and we are unsuccessful in defending ourselves, our business could be significantly impacted. Additionally, if physicians or other providers we work with are found non-compliant, they may face sanctions including exclusion from government-funded healthcare programs, which may adversely affect our business.

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

If regulatory authorities approve any of our drug candidates, manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and record-keeping will be subject to extensive ongoing regulatory requirements. Approvals may also include limitations on indicated uses, conditions of approval, or requirements for costly post-marketing studies including Phase IV clinical trials. Subsequent discovery of previously unknown problems with approved drugs, manufacturing processes, or failure to comply with regulatory requirements may result in marketing or manufacturing restrictions, product withdrawals or recalls, fines, warning letters, holds on clinical trials, refusal to approve pending applications, suspension or revocation of licenses, drug seizure, or civil, administrative, or criminal penalties. Government investigations could require significant time and resources and generate negative publicity. Regulatory policies may change or new regulations may prevent or delay approval of our drug candidates. Failure to maintain regulatory compliance could result in loss of approvals, significantly harming our business and financial condition.

RISKS RELATING TO OUR OPERATIONS

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

Our future financial performance and our ability to commercialize our drug candidates will also depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies. For details, see “Business — Business Strategy.” In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to identify and develop promising drug candidates in the competitive global and PRC biopharmaceutical market, effective coordination and integration of new facilities and new teams that we may develop, successful hiring and training of personnel, as well as effective and efficient financial and management control and quality control. We cannot assure you that we will be able to execute our business strategies and manage any future growth effectively and efficiently, and any failure to do so may materially and adversely affect our ability to capitalize on new business opportunities.

RISK FACTORS

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

Our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. We may not be successful in promoting our brands to remain competitive. In addition, we may engage various third parties to expand our commercialization network and increase market access for our drug candidates, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties. Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrongdoing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such regulatory inquiries, investigations or actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

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

The loss of any senior management could materially affect our business, and our employment agreements do not prevent executives from terminating employment at any time. Recruiting and retaining qualified scientific, technical, clinical, sales, and marketing personnel is critical to our success. The share incentives that we provide vest over time may be affected by share price movements and may be insufficient to counteract more lucrative offers from competitors.

Competition for qualified employees in the pharmaceutical industry is intense and the pool of qualified candidates is limited. The departure of senior management or key personnel may disrupt our drug development progress and be difficult to replace due to the specialized skills required. Any inability to attract, retain, train, or motivate qualified personnel could materially affect our business, financial condition, and prospects.

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

Our management or directors may become party to litigation, legal disputes, claims, or administrative proceedings arising in the ordinary course of business, including matters relating to product liability, environmental issues, breach of contract, employment disputes, and intellectual property rights. Involvement in such proceedings may distract management attention and consume resources, and matters initially not material may escalate. If we cannot successfully defend ourselves, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Negative publicity from such proceedings may damage our reputation, and adverse verdicts could require significant monetary damages or suspension of related business activities, materially affecting our business, financial condition, and results of operations.

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

We maintain industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. The existing insurance coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. 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.

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

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

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

We have leased certain properties in China primarily used as our offices and R&D facilities. Currently, six of our lease agreements were not registered. We may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future.

As our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

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

If we experience material system failure or security breach and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. Likewise, we partially rely on our partners for research and development of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

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

We plan to explore market opportunities overseas, and we intend to identify and collaborate with reputable local partners that have proven track record to maximize the global value of our drug candidates. We will also continue seeking licensing and co-development opportunities with global multinational companies, and expand our global clinical programs. For more details, see “Business — Business Strategy.”

Such activities may subject us to additional risks, including: increased expenses or management distraction from license and collaboration arrangements; political and economic instability and geopolitical tensions; differing international regulatory requirements; longer payment cycles and collection difficulties; difficulty enforcing contracts in local jurisdictions; reduced intellectual property protection; unexpected changes in tariffs, trade barriers, and regulations; adverse currency exchange rate changes; compliance with foreign tax, employment, and labor laws; and business interruptions from geopolitical events or natural disasters.

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

We are susceptible to constantly changing international economic, regulatory, social, and political conditions, and local conditions in foreign countries and regions. Tensions and political concerns between China and other countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. China’s political relationships with foreign countries and regions may affect the prospects of our relationship with third parties, such as business partners, suppliers, and future customers. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. The imposition of tariffs and other trade restrictions by the U.S. and other jurisdictions could disrupt cross-border operations and global supply chains. For example, beginning in February 2025, the U.S. government implemented increased tariffs on certain Chinese imports across multiple sectors, to which China responded with retaliatory tariffs on U.S. goods. These measures led to periods of escalating trade tensions, including instances where tariff rates reached triple-digit levels. While the U.S. and China announced temporary trade agreement in October 2025 following bilateral negotiations, which included partial tariff reductions, the long-term stability of these measures remains uncertain. We cannot predict how tariff policies in the U.S. and other countries may further evolve or anticipate the full impact of subsequent developments in such policies on our business. Any tensions and political concerns between China and the relevant foreign countries or regions may cause a decline in the demand for our future products and adversely affect our business, financial condition, results of operations, cash flows and prospects. Rising trade and political tensions, as well as changes in relevant government policies could reduce levels of trades, investments, technological exchanges and other economic activities between China and other countries and regions.

During the Track Record Period and up to the Latest Practicable Date, we had not been affected by the abovementioned geopolitical tensions in any material respect, considering that (i) all our drug candidates remain in the development stage and we had not generated any revenue from the sales of commercialized products; and (ii) the scale of R&D activities conducted by our subsidiary in the U.S., Newave, currently represents a relatively small portion of our overall operations. For the years ended December 31, 2024 and 2025, our research and development expenses attributable to Newave were RMB33.4 million and RMB34.9 million, respectively. As we are initiating a global Phase III head-to-head clinical trial of LP-168 versus pirtobrutinib in patients with R/R CLL/SLL, we expect to record increased R&D expenses attributable to Newave in the future. As such, there is no assurance as to how the U.S.-China trade disputes and other tensions might develop or whether there will be any changes to the scope and extent of businesses that will be subject to such tariffs, sanctions and export controls, and restrictive measures.

In addition, we or our business partners, including our CROs and CDMOs, may become subject to the recently enacted BIOSECURE Act aiming at discouraging federal contracting with entities that use biotechnology equipment or services provided by certain Chinese biotechnology companies. If we or our business partners were to be listed as or designated as “biotechnology companies of concern,” our ability and our business partners’ ability to engage in business with the U.S. government or with companies that engage in business with the U.S. government may be limited, which could disrupt or diminish our business activities. Additionally, in such event, we may be required to transition certain activities, such as CRO and CDMO services, to alternative providers, which could result in significant delays, increased costs and potential disruptions to our development programs and supply chain. During the Track Record Period and up to the Latest Practicable Date, we did not have business relationship with any entity fall within the category of “biotechnology companies of concern” as defined under the BIOSECURE Act. We have implemented internal control measures designed to mitigate the risks that may arise from the potential designation of our third-party partners under the BIOSECURE Act. These measures include the identification and qualification of alternative suppliers and service providers across our research and development, clinical trial and manufacturing operations, as well as the development

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of transition plans to facilitate the migration of activities should such a transition become necessary. We are actively monitoring legislative and regulatory developments related to the BIOSECURE Act and conducting ongoing assessments of our third-party relationships to ensure that our contingency arrangements remain current and effective. However, any delay in identifying and entering into commercially reasonable business relationship with a new partner could harm our ability to develop products on time or within budget, which could materially adversely affect our business, financial condition and results of operations.

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

Natural disasters, health epidemics, acts of war or terrorism, or other factors beyond our control may adversely affect our operations. Such events could materially disrupt our business, delay clinical trials, and affect the operations of our business partners and third-party collaborators. Any of these events could cause uncertainties in the regions where we conduct business and materially and adversely impact our business, financial condition, and results of operations.

Changes in the economic, political, social conditions, as well as government policies and the interpretation and enforcement of laws, rules and regulations, in the regions where we operate may affect our business, financial condition, results of operations and prospects.

Our business, financial condition, results of operations and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the regions where we operate. Any slowdown in the economic growth of the regions where we operate may reduce the demand for the products we promote and sell and could adversely affect our business, financial condition, results of operation and prospects.

We are subject to governmental regulations on currency exchange.

The convertibility of Renminbi into foreign currencies and the remittance of funds into and out of China are subject to PRC foreign exchange regulations, which require approvals or registrations for transactions such as repaying foreign currency loans. Under the Circular 37, PRC domestic residents must register with SAFE or its local branches for offshore investment activities through special purpose vehicles and update such registrations upon any changes. Failure by our PRC resident shareholders to complete or update these registrations may prevent our PRC subsidiaries from distributing profits or other proceeds to us, or us from making additional capital contributions. Although the subsequent Notice 13 allows qualified banks to handle such filings instead of SAFE, we cannot assure compliance by all relevant shareholders. Any non-compliance may result in fines, penalties, or restrictions under PRC law and could materially and adversely affect our operations and our ability to distribute profits.

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

Under the EIT Law, an enterprise established outside China with “de facto management bodies” within China is considered a “resident enterprise” subject to PRC enterprise income tax on global income. Under certain circulars and bulletins issued by the STA, offshore enterprise controlled by a PRC enterprise is regarded as a PRC tax resident if: (i) day-to-day management is primarily in the PRC; (ii) financial and human resource decisions are made or approved in the PRC; (iii) primary assets, accounting books, and records are maintained in the PRC; and (iv) at least 50% of voting board members or senior executives habitually reside in the PRC. If determined to be a resident enterprise, we may be subject to 25% enterprise income tax on worldwide income. Dividends paid to non-PRC shareholders and capital gains from share sales may be subject to 10% tax for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders, potentially withheld at source.

RISK FACTORS

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

Most of our assets are in the PRC and most of our directors and officers reside there, making it potentially difficult to effect service of process outside the PRC. The PRC lacks treaties for reciprocal recognition and enforcement of civil judgments with the United States and many other countries, which may create difficulties enforcing judgments against us or our directors and officers. The current arrangement between Mainland China and Hong Kong establishes a mechanism for reciprocal recognition and enforcement of civil and commercial judgments without requiring a choice of court agreement. However, as judgments remain subject to case-by-case review, there is no assurance that all Hong Kong court judgments will be recognized and enforced by Mainland courts.

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

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of the SAFE. Additionally, if we finance such subsidiary by means of additional capital contributions, these capital contributions must be registered, reported or filed with certain government authorities, including the Ministry of Commerce (the “MOFCOM”), the State Administration for Market Regulation (the “SAMR”) and the SAFE or their local counterparts. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our subsidiaries or any of their respective subsidiaries. If we fail to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries’ liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments. As a result, this may have a material adverse effect on our business, financial condition and results of operations.

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

We are a holding company registered in the Cayman Islands by way of continuation, and we may rely on dividends and other distributions on equity that may be paid by our subsidiaries for our cash and financing requirements. 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, our PRC subsidiaries are required to set aside at least 10% of its after-tax profits each year, after making up previous years’ accumulated losses, if any, to fund certain statutory reserve funds, until the aggregate amount of such a fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. 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.

RISK FACTORS

Certain PRC regulations establish procedural requirements for some acquisitions of PRC companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

PRC regulations on mergers and acquisitions by foreign investors establish additional procedures and security review requirements. Mergers and acquisitions raising national defense or security concerns are subject to Ministry of Commerce review. Under the Measures on the Security Review of Foreign Investment, foreign investors must declare security reviews prior to investments in important sectors including information technology, financial services, and key technologies. Additionally, PRC anti-monopoly enforcement has strengthened, and authorities may require filings for transactions that may exclude or limit competition regardless of threshold standards. Complying with these requirements could be time-consuming and may delay or inhibit our ability to complete acquisitions, affecting our ability to expand our business.

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

Under SAFE regulations, PRC citizens and non-PRC citizens residing in China for one year or more who participate in stock incentive plans of overseas listed companies must register with SAFE through a domestic qualified agent and retain an overseas-entrusted institution to handle stock option exercises and share transactions. We and our employees will be subject to these regulations upon completion of the [REDACTED], and failure to complete registrations may result in fines. Additionally, under STA circulars, employees in China who exercise share options or receive restricted shares are subject to PRC individual income tax. Our PRC subsidiary must file relevant documents and withhold taxes, and failure to comply may result in sanctions from tax authorities.

RISKS RELATING TO THE [REDACTED]

There has been no prior market for our Shares and their liquidity and market price following the [REDACTED] may be volatile.

There was no [REDACTED] for our Shares prior to the [REDACTED]. There can be no guarantee that a [REDACTED] for our Shares with adequate liquidity and [REDACTED] will develop and be sustained following the completion of the [REDACTED]. In addition, the [REDACTED] of our Shares is expected to be fixed by agreement between the [REDACTED] (for itself and on behalf of the [REDACTED]) and us, which may not be indicative of the market price of our Shares following the completion of the [REDACTED]. If an active [REDACTED] for our Shares does not develop following the completion of the [REDACTED], the market price and liquidity of our Shares may be materially and adversely affected.

Potential [REDACTED] will experience immediate and substantial dilution as a result of the [REDACTED] and could face dilution as a result of future equity financings.

As the [REDACTED] of our Shares is higher than the net tangible assets per Share immediately prior to the [REDACTED], purchasers of our Shares in the [REDACTED] will experience an immediate dilution in [REDACTED] adjusted net tangible assets. Our existing Shareholders will receive an increase in the [REDACTED] adjusted net tangible asset value per Share of their shares. In addition, holders of our Shares may experience further dilution of their interest if the [REDACTED] exercise the [REDACTED] or if we issue additional shares in the future to raise additional capital.

RISK FACTORS

Future or perceived sales of substantial amounts of our Shares could affect their market price.

Future sales of substantial amounts of our Shares or other securities relating to our Shares in the [REDACTED], or the issuance of new Shares or other securities relating to our Shares, or the perception that such sales or issuances may occur could all cause a decline in the market price of our Shares. Future sales, or perceived sales, of substantial amounts of our securities or other securities relating to our Shares, including part of any future [REDACTED], could also materially and adversely affect the prevailing [REDACTED] of our Shares and our ability to raise capital in the future at a time and at a price which we deem appropriate.

Our Single Largest Group of Shareholders have substantial influence over the Company, and their interests may not always be aligned with the interests of our other Shareholders.

Our Single Largest Group of Shareholders collectively has significant influence in determining the outcome of any corporate transaction or other matter submitted to the Shareholders for approval, including but not limited to mergers, privatizations, consolidations and the sale of all, or substantially all, of our assets, election of directors, and other significant corporate actions. Immediately following the completion of the Share Subdivision and the [REDACTED] and assuming the [REDACTED] is not exercised, our Single Largest Group of Shareholders will be together entitled to control in aggregate approximately [REDACTED]% of our total issued share capital and thus remain as the Single Largest Group of Shareholders upon [REDACTED]. The interests of Single Largest Group of Shareholders might differ from the interests of our other Shareholders. Any conflict of interest between Single Largest Group of Shareholders and our other Shareholders may also materially and adversely affect aspects such as the decision and implementation of our business plans, which may, in turn, affect our operations and prospects.

We may not pay any dividends in the future.

Our ability to pay dividends will depend on whether we are able to generate sufficient earnings. Distributions of dividends shall be decided by our Directors at their discretion and will be subject to the approval of the general meeting. A decision to declare or to pay dividends and the amount thereof depend on various factors, including but not limited to our results of operations, cash flows and financial position, operating and capital expenditure requirements, distributable profits as determined under the applicable accounting standards (whichever is lower), our Articles of Association and other constitutional documents, the PRC Company Law, the Cayman Companies Act, the common law of the Cayman Islands and any other applicable laws and regulations, market conditions, our strategy and projection for our business, contractual restrictions and obligations, taxation, regulatory restrictions and any other factors from time to time deemed by our Directors as relevant to the declaration or suspension of dividends. As a result, there can be no assurance whether, when and in what form we will pay dividends in the future. Subject to any of the above constraints, we may not be able to pay dividends in accordance with our dividend policy.

You should only rely on the information included in this document to make your [REDACTED] decision, and we strongly caution you not to rely on any information in press articles or other media coverage relating to us, our Shares or the [REDACTED].

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

RISK FACTORS

Certain facts, forecasts and statistics in this document relating to the biopharmaceutical industry are derived from official government sources and such information may not be fully reliable.

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

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

This document contains forward-looking statements with respect to our business strategies, operating efficiencies, competitive positions, and growth opportunities for existing operations, plans and objectives of management, certain [REDACTED] information, and other matters. The words “will,” “expect,” “anticipate,” “estimate,” “believe,” “going forward,” “ought to,” “may,” “seek,” “should,” “intend,” “plan,” “projection,” “could,” “vision,” “goals,” “objective,” “target,” “schedule,” “predict,” “aim,” “intend,” “consider,” “would,” “continue” and “outlook” and the negative of these terms and other similar expressions identify a number of these forward-looking statements. These forward-looking statements are necessary estimates reflecting the best judgment of our Directors and management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. As a result, these forward-looking statements should be considered in light of various important factors, including those set out in “Risk Factors” in this document. Accordingly, such statements are not a guarantee of future performance and you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to this cautionary statement.