

RISK FACTORS

An [REDACTED] in our H Shares involves various risks. You should carefully consider all the information in this document and in particular the risks and uncertainties described below before making an [REDACTED] in our H Shares. The following is a description of what we consider to be our material risks. The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] of our H Shares could decline and you may lose all or part of your [REDACTED]. You should seek professional advice from your relevant advisors regarding your prospective [REDACTED] in the context of your particular circumstances.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and prospects depend substantially on the success of the development of our drug candidates.

Our business and prospects depend substantially on our ability to advance our drug candidates through preclinical and clinical development and to obtain marketing approvals. The development and approval process is subject to risks and uncertainties, including patient enrollment and trial completion, clinical supply and CMC readiness, protocol amendments or evolving regulatory expectations that may require supplemental data, and the performance, quality and compliance of CROs, CDMOs and other third parties and collaborators, any of which could delay regulatory submissions and approvals. As of the Latest Practicable Date, all of our drug candidates were in preclinical or clinical development, and there can be no assurance that any candidate will generate sufficient safety and efficacy data, progress as planned or obtain regulatory approvals. Any failure to achieve key development milestones, or any significant delay, cost overrun or interruption, could require additional studies, prolong timelines, increase our funding needs or result in the suspension or discontinuation of development, which could materially and adversely affect our business, financial condition and results of operations.

We face intense competition and rapid technological change, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The biopharmaceutical industry in which we operate is intensely competitive and subject to rapid and significant technological changes. Our Core Product ABP-671 and our other drug candidates may compete with approved and emerging therapies for gout and related indications, including low-cost generics that are widely used, such as xanthine oxidase inhibitors (allopurinol and febuxostat) and URAT1 inhibitors (benzbromarone and probenecid), as well as novel xanthine oxidase inhibitors, next-generation URAT1 inhibitors, urate oxidase and combination approaches. Competitors, including multinational pharmaceutical companies, may have greater resources and may advance programs faster, obtain broader or earlier regulatory approvals, or demonstrate superior efficacy, safety, convenience or cost, which could limit physician adoption and payer support for ABP-671 and other candidates. For details, see “Business — Competition” and “Industry Overview.”

Our competitive position may also depend on the execution of our commercial arrangements. In Chinese Mainland, Hong Kong and Macau, we expect to rely on our exclusive commercial collaboration with CMS, and there is no assurance that pricing and reimbursement outcomes (including NRDL negotiations) will be favorable or achieved on our expected timeline. Outside these markets, we intend to collaborate with multinational pharmaceutical companies on ABP-671, and the timing, scope and performance of any partner-led development and registration activities are uncertain. If competitors establish market positions earlier or reimbursement benchmarks tighten, our ability to compete and our financial condition and prospects could be materially and adversely affected.

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

Clinical development is lengthy, costly and inherently uncertain. We may be unable to initiate or continue trials as planned, such as when regulators, ethics committees or other review bodies do not approve a trial or a proposed site, when trials are suspended or terminated due to safety findings or lack of efficacy, or when adverse events or undesirable side effects occur. Our timelines and costs may also be affected by our ability to contract with and manage CROs and trial sites, to secure

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adequate clinical supply and address CMC and quality issues, to enroll and retain patients at the expected rate, and by intellectual property-related disputes or an inability to obtain or maintain appropriate protection for our candidates.

Even where early data is encouraging, later-stage trials may fail to replicate safety or efficacy results. Trial outcomes may vary due to differences in patient populations and demographics, baseline conditions and concomitant medications, adherence to dosing, sample size, and the number and location of sites and regions. Any such setbacks could delay, complicate or prevent the completion of our clinical programs and the submission for, or receipt of, regulatory approvals, and materially and adversely affect our business, financial condition and results of operations.

If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.

If our drug candidates do not demonstrate safety and efficacy to the satisfaction of regulatory authorities, or otherwise yield negative or only modest clinical results, regulators may delay, limit or deny approvals, require additional trials or other studies beyond our current plans, or impose approval conditions, including narrower indications, enhanced warnings or contraindications, medication guides and/or risk management requirements and distribution or use restrictions. Any conditional approval may also require confirmatory and additional safety studies, and if such studies do not verify the expected clinical benefit or acceptable safety profile, the approval may be withdrawn. Any of the foregoing could increase our costs, delay or prevent regulatory submissions or approvals for our drug candidates and materially and adversely affect our business, financial condition and prospects.

We may not be able to discover or develop new drug candidates, or to expand the therapeutic opportunities for our drug candidates.

Besides the continued clinical testing, potential approvals and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to discover and develop additional drug candidates. We may not be able to successfully do so in the future. Moreover, some drug candidates may be technically challenging to develop and manufacture. Drug candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. In addition, while we may seek to expand the indications of our existing drug candidates, such efforts may not be successful.

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

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

As we have limited financial and managerial resources, we focus on research programs and drug candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later may prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. We may also allocate significant internal resources to a drug candidate in a therapeutic area in which a partnership would have been more advantageous. Either scenario could materially and adversely affect our future growth and prospects.

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

Results of trials conducted by us or by our collaboration partners with respect to our drug candidates could reveal a high and unacceptable severity or prevalence of certain adverse events ("AEs"). In such an event, such trials could be suspended or terminated and the NMPA, the FDA, the TGA or other comparable regulatory authorities could order us or our collaboration partners, as applicable, to cease further development of, or deny approval of, our drug candidates for any or all

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targeted indications. AEs related to our drug candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. If safety issues are identified after any approval, regulators may impose additional warnings or risk-management requirements, including restrictions on distribution and/or post-marketing studies, or withdraw approvals or revoke licenses, and we or our collaboration partners may be required to suspend marketing. In addition, the use of our drug candidates in combination with third-party drugs may present distinct or exacerbated AEs compared with monotherapy, which could further complicate development, labeling and regulatory oversight. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

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

Clinical enrollment is competitive, and patients who might otherwise participate in our studies may enroll in competitors' trials for the same indications, which could prolong timelines, increase costs and delay the generation of data required for regulatory submissions. These risks may be more acute for trials in rare diseases, including those related to ABP-745 for rare inflammatory conditions, where the number of diagnosed and eligible patients is inherently limited and may be further constrained by geographic dispersion, limited disease awareness and diagnosis, and competing studies. If enrollment is slower than expected, we may need to add sites, broaden recruitment efforts or expand into additional regions or countries, which could increase complexity and costs and adversely affect the progress of our clinical development programs.

We have been conducting clinical trials for the same product candidate across multiple jurisdictions, which may expose us to various risks that could adversely affect our product development and commercialization prospects.

We have been conducting clinical trials for certain product candidates in multiple jurisdictions, including the PRC, the U.S. and Australia. The regulatory frameworks and clinical trial requirements differ across these jurisdictions. For example, the NMPA, the FDA, the TGA or other comparable regulatory authorities may have different expectations regarding trial design, patient population, comparator arms, endpoints or statistical methodologies. In certain cases, data generated in one jurisdiction may not be fully accepted by regulators in another jurisdiction without bridging studies or additional local data. In addition, we may face challenges in data integration and consistency, especially when clinical data are derived under different operational standards or Good Clinical Practice ("GCP") requirements. These differences may lead to longer development timelines, duplicated efforts, or increased development costs.

Conducting cross-border trials also increases our exposure to compliance and operational risks. For example, we are required to comply with Personal Information Protection Law of the PRC and relevant data export regulations, as well as the U.S. Data Security Program. Any non-compliance may lead to regulatory sanctions, delays in patient enrollment, or invalidated data. Moreover, coordinating multi-jurisdictional trials imposes operational burdens, including differences in investigator experience, site management efficiency, and patient recruitment capacity. As such, our ongoing and planned MRCT may be subject to uncertainty, and any delay, suspension or failure in one or more jurisdictions may materially and adversely affect our product development and commercialization prospects.

Our preclinical programs may experience delays or may never advance to clinical trials.

Some of our product candidates were in the preclinical development stage as of the Latest Practicable Date. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies on safety and efficacy of product candidates to obtain regulatory clearance to initiate clinical trials on humans. We cannot be certain of whether we will be able to timely complete our preclinical studies or generate results that are adequate to support the initiation of subsequent clinical trials. There is also no assurance that the NMPA, the FDA, the TGA or other comparable regulatory authorities will accept our proposed protocols for clinical programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our preclinical programs or that could result in the clinical trial approval from regulatory authorities.

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

We collect, aggregate, process, and analyze data and information from preclinical studies, clinical trials and other research and development programs. We also engage in substantial information gathering following the identification of a potential drug candidate. Such data and information may be fragmented, inconsistently formatted or incomplete, and errors may occur in data capture, entry, processing or analysis. If the data we generate, aggregate or rely upon are inaccurate or incomplete, we may draw incorrect conclusions, experience delays or setbacks in our development programs, and suffer reputational harm. Because regulatory submissions involve complex data processing and validation requirements, errors in how data are stored, handled or submitted could also lead to regulatory challenges, delays or potential liability. We also depend on third parties to collect, monitor and manage data for certain programs and have limited control over their activities. Any deficiencies, inaccuracies or omissions in third-party data could compromise the integrity of our datasets and adversely affect our clinical development progress and prospects.

We invest substantial human and capital resources in research and development, but we cannot guarantee that such efforts will lead to successful outcomes.

In 2024 and 2025, our research and development expenses were RMB338.1 million and RMB179.7 million, accounting for 96.8% and 92.4% of our total operation expenses consisting of R&D expenses and administrative expenses, respectively. We intend to continue to strengthen our technical capabilities in the development of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

We may fail to sufficiently and promptly respond to rapid scientific and technological changes, clinical demand, and market changes in the pharmaceutical industry.

The pharmaceutical industry is characterized by rapid advancements in science and technology and the continuous emergence of new treatment options. Clinical demand for pharmaceutical products may also change rapidly. We may need to adjust our R&D plan, production scale and schedule, and product matrix in response to the evolving clinical demand, customer preferences, sales trends or other market conditions. We cannot assure you that we could sufficiently and promptly respond to these changes in the future, and any such failure may have a material adverse effect on our business, financial condition, and results of operations.

We utilize AI-based tools in certain stages of our drug discovery and development processes as part of our technology platform. Our application of these technologies remains at an early stage, and there can be no assurance that such tools will function as expected or deliver outcomes comparable to those achieved through conventional methods. Any material errors, limitations or bias in the AI models or datasets we use, or changes in applicable regulatory policies governing AI application, could adversely affect our R&D efficiency and results.

RISKS RELATING TO THE COMMERCIALIZATION OF OUR DRUG CANDIDATES

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

Even if our drug candidates receive regulatory approval, they may not achieve or sustain adequate market acceptance. Market acceptance may be affected by a number of factors, including the approved indications; perceptions of safety and efficacy; the extent of differentiation versus existing therapies; the frequency and severity of side effects; the content of the approved label, including any limitations, contraindications or warnings imposed by the NMPA, the FDA, the TGA or other comparable authorities; timing of launch relative to competitors; overall treatment cost and patient out-of-pocket burden; reimbursement coverage; convenience and ease of administration; any physician training or operational requirements; and the effectiveness of sales and marketing efforts. If our products fail to achieve or maintain market acceptance as expected, our ability to generate expected revenues and achieve profitability could be materially and adversely affected.

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The size of the potential market for our drug candidates may be smaller than our estimates.

We estimate the potential patient population and market opportunity for our drug candidates based on assumptions and data derived from third-party sources such as scientific literature, clinic surveys, patient organizations and market research. These sources may be incomplete, outdated or incorrect, and new studies may change the estimated incidence or prevalence of the relevant diseases. If our assumptions are inaccurate, the addressable patient population and market size for our current or future drug candidates could be smaller than we expect. Even if a drug candidate is approved, there is no assurance it will be approved for the line of therapy we target. If we are unable to obtain approval for earlier-line use or for additional indications, the realized market opportunity for our drug candidates may be materially smaller than anticipated.

We have limited experience in launching and marketing drug candidates, and failure to do so will adversely affect our business.

Our operations to date have been largely focused on preclinical studies and conducting clinical trials. We have not yet demonstrated an ability to launch and commercialize any drug products. As a result, our future efforts in product launch and commercialization may involve more inherent risks, take longer, and cost more than it would if we were a company with experience product launch and marketing. Successful commercialization will require us to build, expand and optimize sales, marketing and distribution capabilities, including recruiting, training and retaining qualified personnel, and establishing an effective distribution network. We may compete with other biopharmaceutical companies for experienced commercial talent, and there is no assurance we can build these capabilities in a timely or cost-effective manner, or that newly formed teams will perform effectively. If we are unable to develop adequate internal capabilities, we may rely on third-party collaborators for sales, marketing and distribution, and we may have limited control over their activities, and such arrangements may be difficult to establish or maintain. Any failure to build or enhance our commercialization capabilities could delay launches, limit market acceptance and reduce our expected revenues of our drug candidates, which could adversely affect our business and financial performance.

We may be subject to unfavorable pricing regulations and the reimbursement may be limited or unavailable in certain market segments.

Pricing and reimbursement regimes vary across jurisdictions, and even after obtaining regulatory approval, we may face delays, restrictions or unfavorable outcomes on pricing and reimbursement that could materially limit future commercialization of our drug candidates. In China, pricing of certain drugs and biologics may be subject to government regulation, and reimbursement is a key driver of market uptake. For details about the NRDL and other related matters, see “Regulatory Overview.” There is no assurance that any of our approved products will be included in the NRDL. If our products are not included, sales may depend heavily on patient self-payment, which could reduce competitiveness versus lower-priced or NRDL-listed alternatives. Even if we obtain NRDL inclusion, we may be required to accept price reductions, which could materially reduce our revenues and profitability. In the U.S., coverage and reimbursement decisions are made on a payer-by-payer basis with no uniform policy, and obtaining coverage can be time-consuming and costly, often requiring scientific, clinical and cost-effectiveness data. Even if coverage is obtained, reimbursement rates may be insufficient, may impose patient co-payments that limit uptake, and may not adequately cover required long-term follow-up evaluations. More generally, reimbursement may be delayed, may be more limited than the approved label, and may not cover our costs of research, development, manufacturing, sale and distribution. If we cannot obtain timely and adequate reimbursement at acceptable payment rates, demand for our products and our financial results could be materially and adversely affected.

We have entered into collaboration with third parties in the commercialization of our drug candidates and may seek and enter into additional partnerships in the future. We may not realize the benefits of such partnerships as expected or fail to identify suitable business partners.

We have entered into a collaboration agreement with CMS to commercialize ABP-671 for the treatment of gout in Chinese Mainland, Hong Kong, and Macau. For details, see “Business — Commercialization — Commercialization Arrangement with CMS on ABP-671.” Our ability to successfully commercialize ABP-671 in such markets depends on our commercialization partner’s ability to effectively allocate resources, engage key stakeholders, comply with applicable laws and regulations, and achieve performance objectives. However, we have limited control over its day-to-day operations, and any failure by the partner to perform its obligations could result in delays in market entry, poor commercial uptake, or reputational harm.

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In addition, such arrangement may be subject to early termination due to various reasons, such as failure to meet regulatory or development milestones, underperformance against agreed sales targets, disputes, or other operational or strategic considerations. If the collaboration is terminated, we may face significant disruption to our commercial plans, and may need to rebuild or replace the commercial infrastructure for the affected markets at considerable cost and time.

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We work with various third parties to develop our drug candidates. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our drug candidates, and our business, financial condition and results of operations could be materially and adversely affected.

We work with various third parties to develop, manufacture and, if approved, commercialize our drug candidates, and we remain accountable to regulatory authorities for compliance with applicable protocols, scientific standards and regulatory requirements. Accordingly, deficiencies in third-party performance may result in increased costs, development delays, regulatory findings or the need to repeat studies or remediate manufacturing issues, any of which could materially and adversely affect our business, financial condition and results of operations.

We collaborate with CROs, clinical trial sites, investigators and other clinical service providers to support and conduct elements of our preclinical and clinical studies, including trial operations, monitoring, data management, statistical analysis and related activities. We have limited control over their staffing, quality systems, prioritization and allocation of resources. If they fail to follow our protocols, meet expected timelines, maintain adequate documentation, or comply with applicable regulatory requirements, our studies may be compromised, delayed, suspended or terminated, and the NMPA, the FDA, the TGA or other comparable authorities may consider the resulting data unreliable or insufficient and require additional work before approving any marketing application. In addition, replacing or adding CROs, sites or vendors may involve significant transition efforts, additional cost and delays, and we may not be able to do so on commercially reasonable terms or at all.

We also collaborate third-party manufacturers, including CDMOs. As of the Latest Practicable Date, we had not commercialized any drug candidates, and we do not have our own commercial-scale manufacturing facilities. Our ability to progress clinical development and, if approved, to supply the market depends on our CDMOs' ability to manufacture drug substance and drug product in a timely manner, at required volumes, and in accordance with specifications and applicable regulatory standards. Reliance on CDMOs exposes us to risks including limited capacity and manufacturing slots, scheduling conflicts, supply chain disruptions, cost fluctuations, deviations, batch failures, and reduced oversight of manufacturing and quality processes. Further, CDMOs are subject to regulatory inspections and compliance requirements, and any adverse inspection outcomes or other compliance failures may lead to supply interruptions, additional remediation or validation work, delays in regulatory submissions or approvals, or, if applicable, recalls and other enforcement actions.

Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels. Issues may arise during the manufacturing process for reasons including: (i) equipment malfunction, (ii) failure to follow specific protocols and procedures, (iii) problems with raw materials, (iv) changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, (v) changes in the type of products produced, (vi) advances in manufacturing techniques, (vii) physical limitations that could inhibit continuous supply, and (viii) the occurrence of natural disasters. If problems arise during the production process of certain future products, a batch or several related batches of such product may have to be discarded, which may cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If problems are not discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

In addition, we may work with other third parties, including suppliers of raw materials and components, third-party testing laboratories, and other business partners. Certain materials may be sole-sourced or difficult to qualify, and any inability by suppliers engaged by our or our CROs or CDMOs to provide adequate quantities of acceptable-quality materials on a timely basis, could delay or halt our development and manufacturing activities. If third-party testing is not properly performed or test data are unreliable, patient safety could be jeopardized, and regulators may impose restrictions until deficiencies are remediated. We have limited control over collaborators' priorities and performance, and any delay, breach, termination or underperformance could adversely affect study execution, regulatory filings and approvals, and commercialization efforts. Moreover,

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engaging third parties typically requires us to share proprietary information and sensitive clinical information, increasing the risk of unauthorized disclosure or misuse. Any of the foregoing could materially and adversely affect our business, prospects, financial condition and results of operations.

We relied on a limited number of suppliers and were dependent on our largest supplier during the Track Record Period.

During the Track Record Period, our purchases from our five largest suppliers in each year in aggregate amounted to RMB287.7 million and RMB125.1 million, representing 87.5% and 66.7% of our total corresponding purchases, respectively. Our purchases from the largest supplier in each year during the Track Record Period, which is a CRO headquartered in the U.S. we engaged for the conduct of our U.S. clinical trials, accounted for 56.8% and 28.1% of our total corresponding purchases, respectively. Our reliance on a limited number of suppliers, and in particular on a single largest supplier, may expose us to risks relating to supply continuity, pricing, quality and contractual disputes. If any of these key suppliers, especially our largest supplier, is unable or unwilling to continue to supply to us in a timely manner, experiences quality control issues, fails to comply with regulatory requirements, significantly increases prices or otherwise becomes unable to fulfill our supply needs, we may not be able to identify suitable alternative suppliers or secure regulatory approvals for such suppliers in a timely and cost-effective manner, or at all. As a result, our business operations, R&D progress, financial condition and results of operations could be materially and adversely affected.

Our relationships with certain principal investigators, key opinion leaders, physicians and other industry experts may affect the clinical development and future marketing of our products.

Our relationships with principal investigators, key opinion leaders (“KOLs”), physicians and other industry experts play an important role in our research and development and marketing activities. We have established extensive interaction channels with principal investigators, KOLs, physicians and experts to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, KOLs, 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.

We may not be able to maintain effective quality control and quality assurance.

The quality of our pipeline products for research and development purposes and future commercialization depends and will depend significantly on the effectiveness of our quality control and quality assurance. That, in turn, depends on factors such as the production processes, the quality and reliability of equipment used, the capabilities of the CDMO partners we engage and our ability to ensure that they adhere to our quality control and quality assurance protocol. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

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

We are a clinical stage biotechnology company with a limited operating history. We have not yet demonstrated an ability to successfully obtain marketing approvals for, or commercialize, our drug candidates. To date, we have no products approved for commercial sale and have not generated any revenue from product sales. As a result of our limited operating history, it may be difficult for investors to evaluate our business, assess our prospects or accurately predict our future performance. We may face risks and difficulties commonly experienced by early-stage companies in developing, manufacturing and, if approved, commercializing novel therapeutics. If we are unable to successfully manage these risks and difficulties, our business, financial condition and results of operations could be materially and adversely affected.

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

We have incurred net losses since our inception and expect to continue to incur net losses for the foreseeable future. We have not generated any revenue from commercial product sales and have no products approved for commercial sale. We have incurred net losses in 2024 and 2025 of RMB434.1 million and RMB534.4 million, respectively, which were primarily attributable to expenses incurred by our research and development activities. Our losses may increase as we continue to invest in our pipeline and scale our operations, including to support later-stage clinical development, regulatory submissions and potential commercialization, and as we incur additional costs associated with operating as a [REDACTED] following the completion of the [REDACTED]. The extent of our future losses will depend on multiple factors, including the pace of our spending, clinical and regulatory outcomes, any revenues if products are approved and launched, and the timing and amount of milestone and other payments payable to, or receivable from, third parties. If our product candidates fail in clinical development, do not obtain regulatory approval or, even if approved, do not achieve market acceptance, we may never achieve or maintain profitability, which could materially and adversely affect our business, financial condition and results of operations.

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

We had cash used in operating activities of RMB368.4 million and RMB119.0 million in 2024 and 2025, primarily for our research and development activities. We incurred net current liabilities of RMB963.8 million, RMB1,333.0 million as of December 31, 2024 and 2025, respectively. We expect to continue experiencing net cash outflows from our operating activities in the future. For details, see “Financial Information — Liquidity and Capital Resources — Cash Flows.” Our forecast of the period of time through which our capital resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

During the Track Record Period, we funded our operations primarily through proceeds from equity financing. We expect our expenses to increase significantly as we advance and expand our clinical and preclinical programs, conduct additional trials and pursue regulatory approvals, and, if any product candidates are approved, build commercialization capabilities and meet post-approval obligations, while also incurring additional costs associated with operating as a public company in the future. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

We are exposed to risks in connection with the fair value change of financial assets at FVTPL.

During the Track Record Period, we invested in financial products which represent wealth management products and structured deposits with banks. The returns of our investments in wealth management products were not guaranteed, and net changes in the fair value of our investments are recorded as our other income or losses, and therefore directly affect our results of operations. Any change in the key valuation assumptions may lead to different valuation results and, in turn, changes in the fair value of these financial assets at FVTPL. We may continue to invest in wealth management products in the future, and we cannot guarantee that we will not experience losses with respect to such investments in the future.

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

We have adopted our employee incentive scheme for the purpose of granting share-based compensation awards to management members and core technical and operational personnels to incentivize their performance and align their interests with ours. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation awards to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may affect our financial condition and results of operations. We may re-evaluate the

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vesting schedules, lock-up period, exercise price or other key terms applicable to the arrangements under our currently effective employee stock option plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following the [REDACTED].

We benefit from certain government subsidies, the expiration of or changes to which could adversely affect our profitability.

We have historically received various government subsidies, including subsidies from different local governmental authorities to support the research and development for our drug candidates. We recognized government grants as other income of RMB1.4 million and RMB1.1 million in 2024 and 2025, respectively. There is no assurance that we could continue to enjoy or maintain government subsidies at the historical levels. Any change, suspension or termination of these government subsidies, or government financial incentives in other forms, may have a negative impact on our business, financial condition and results of operations.

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

The Renminbi has fluctuated against the Hong Kong dollar and the U.S. dollar, at times significantly and unpredictably. In 2024, we recorded net foreign exchange gains of RMB0.9 million and recorded net foreign exchange losses of RMB1.8 million in 2025. There is no assurance that we will continue to incur foreign exchange gains in the future or our foreign exchange losses will not incur in the future. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and U.S. dollar in the future.

The [REDACTED] from the [REDACTED] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our H Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to complete filings with and obtain approvals from the State Administration of Foreign Exchange of the PRC (the “SAFE”) before converting significant sums of foreign currencies into Renminbi. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

RISKS RELATING TO 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 products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize our products may be adversely affected.

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important primarily by filing patent applications in China, the U.S., and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

The issuance, scope, validity, enforceability and commercial value of patents are inherently uncertain. Patent examination may require us to narrow our claims, potentially reducing protection, and undiscovered prior art or defects in patents or applications may prevent issuance or render issued patents invalid or unenforceable. Even if patents are granted, third parties may challenge them in litigation or administrative proceedings, and adverse outcomes could narrow or invalidate our claims, limit our ability to exclude others, or require us to obtain licenses or otherwise prevent

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us from commercializing certain drug candidates without infringing third-party intellectual property rights. In addition, intellectual property laws and enforcement vary across jurisdictions and may be costly, time-consuming and unpredictable, which may limit our ability to prevent third parties from practicing our inventions, or from selling, importing or exporting competing products, and competitors may design around our patents.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (the "CNIPA"), the United States Patent and Trademark Office (the "USPTO"), and other applicable patent authorities over the lifetime of a patent. There are situations in which inadvertent failures or non-compliances 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. Such non-compliance events include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits.

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

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the duration of a patent is generally 20 years from the date of application for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Even if patents covering our drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates could expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor's product or product use.

Manufacturers of generic drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be materially and adversely affected. On the other hand, if we launch our drug candidates prior to the expiration of patents for any competing products, we may face potential claims for patent infringement.

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

The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could put our patents at risk of being invalidated or interpreted narrowly, could

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

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

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks, and may not be registered in all the necessary or desirable jurisdictions and categories in which we intend to sell our future products or provide our future services. Our trademarks may not be approved by one or more governmental trademark offices or may not be approved for use on our products or services by regulatory authorities. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

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

In addition to our issued patents and pending patent applications, we rely on trade secret and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We may need to share trade secrets with our employees or third-party collaborators, such as scientific collaborators, sponsored researchers, CROs and CDMOs, consultants, advisers and other third parties. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches.

Our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially and adversely affect our business, financial condition, and results of operations. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

If we fail in prosecuting or defending any claims in relation to our trade secrets, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, be a distraction to our management and scientific personnel and have a material adverse effect on our business, financial condition, results of operations and prospects. As of the Latest Practicable Date, we were involved as the plaintiff in an ongoing legal proceeding seeking remedies against an independent third party for its misappropriation of our trade secrets in its own R&D activities. The third party had also initiated a counter-litigation against us and our Single Largest Shareholder. While we believe our claims are well-founded, we cannot predict the final outcome of the legal proceedings. We, however, do not expect the disputes with the third party to have any material adverse impact on the R&D or commercialization of our drug candidates, as the disputes do not involve any material patents and patent applications of our Core Product ABP-671 and other pipeline assets. We also do not expect such disputes to have any material adverse impact on our results of operations, financial position or growth prospects. For details, see "Business – Legal Proceedings and Non-Compliance – Legal Proceedings."

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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.

Patent and other intellectual property litigation and administrative proceedings are common in the biopharmaceutical industry, and we may become involved in such disputes. Third parties may challenge, infringe, or misappropriate our patents and other intellectual property rights, and we may be required to enforce or defend our rights, which can be expensive, time-consuming and distracting, particularly where claimants have greater resources than we do. Such proceedings could result in adverse rulings affecting our ownership or control of our intellectual property, narrowing or limiting the protection available to us, or determinations that our patents are invalid or unenforceable or do not cover the challenged technology. We may not obtain injunctive relief and may receive only monetary damages that are not an adequate remedy, and enforcement efforts may trigger counterclaims, expose us to substantial liability, and deter current or prospective collaborators from licensing, developing or commercializing our drug candidates, any of which could materially adversely affect our business.

We cannot guarantee that our research, development, manufacture, use or commercialization of our drug candidates and any future products does not and will not infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. We may fail to identify relevant third-party patents or applications, and because scientific and patent publications often lag behind discoveries, we cannot be certain that we were the first to invent or file with respect to our drug candidates or their uses, that our applications will not be treated as competing applications, or that published pending applications will not later be amended to cover our products or their use. If third parties assert infringement or trade secret misappropriation claims, even if we believe they lack merit, a court could find the third-party rights valid, enforceable and infringed, which could block our ability to develop or commercialize the relevant product unless we obtain a license or until the third-party rights expire or are finally determined to be invalid or unenforceable. Defending such claims could require substantial expenditures and, if we are found to infringe, could result in substantial damages, including enhanced damages and attorneys' fees in the event of willful infringement.

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

Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in China, the U.S., Australia, and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, there are periodic proposals for changes to the patent laws in China, the U.S., Australia, and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Changes in patent law and regulations in applicable countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our current and future owned and licensed patents.

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

The degree of protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business nor permit us to maintain our competitive advantage. For example, third parties may be able to develop and commercialize drug candidates that are the same as or similar to ours but are not covered by the claims of patents we own or exclusively license; may independently develop similar or alternative technologies or duplicate our technologies without infringing our intellectual property rights; may conduct research and development in countries where we do not have patent rights and use information learned from those activities to develop competing products for sale in our primary commercial markets; and we may be unable to develop additional technologies that are patentable.

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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 evolving 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.

The jurisdictions in which we operate or intend to operate, including China, the United States and Australia, regulate product development and approval, manufacturing, and marketing, sales and distribution through stringent and evolving regulatory regimes. In China, the U.S, Australia and other jurisdictions, the regulations relating to the biopharmaceutical industry and the healthcare system are subject to change and varying interpretations, which may result in continuing uncertainty regarding compliance matters and additional costs. If regulators determine that we lack required approvals or permits, impose new requirements or restrictions, or determine that we have failed to comply at any stage of development, approval or after commercialization, they may take actions including refusing to approve pending applications, imposing clinical holds, withdrawing approvals, revoking licenses, requiring voluntary or mandatory recalls, seizing products, suspending production or distribution, imposing injunctions, fines, confiscation of income, restitution or disgorgement, refusing government contracts, and pursuing civil or criminal penalties. We may be required to obtain clearances from agencies such as the NMPA, FDA or TGA for IND submissions to initiate clinical trials and to submit NDAs or comparable applications for marketing approval, and any noncompliance may lead to termination of research, disqualification of data, restrictions or bans on sales, and other punitive actions. Even if we successfully defend against alleged violations, investigations or enforcement actions could result in significant legal costs, diversion of management attention, and reputational harm.

If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our target markets, our business may be subject to actual or perceived harm.

Our drug candidates may fail to obtain regulatory approval for many reasons, including regulators' disagreement with the design, conduct or interpretation of our preclinical studies or clinical trials; failure to demonstrate adequate safety, efficacy and potency for the proposed indication; failure to achieve required statistical significance; failure to comply with or pass inspections or audits under applicable standards, such as GCP at clinical sites and cGMP across manufacturing; deficiencies identified in our or our third-party partners' manufacturing processes; insufficient clinical data to support an NDA (or comparable submission); changes in approval policies, regulations or data requirements that render our existing data inadequate; or inability to keep pace with scientific or technological expectations reflected in evolving regulatory standards. Regulators may also require additional information or further preclinical or clinical studies, which could delay or prevent approval and commercialization. The regulatory approval processes of the NMPA, the FDA, the TGA and other comparable regulatory authorities are time-consuming and may evolve over time. If we are unable to obtain required regulatory approvals for our drug candidates in our target markets without undue delay, our business may be harmed, including through actual or perceived damage to our reputation, and we may incur additional time, effort and expense to comply with differing requirements across jurisdictions. Even if approval is obtained, regulatory authorities may approve a drug candidate for narrower or different indications than requested, impose significant post-marketing study requirements, or otherwise condition approval in ways that increase costs, delay broader commercialization, or reduce the market opportunity, any of which could materially harm the commercial prospects of our drug candidates.

We may not obtain or maintain approval for our drug candidates to be eligible for an expedited registration pathway as innovative or breakthrough therapy.

To date, we have not received any expedited registration pathway as innovative or breakthrough therapy. If we intend but are unable to obtain or maintain eligibility for expedited development, review or registration pathways, such as innovative drug, fast track or breakthrough therapy programs, from the NMPA, the FDA, the TGA or comparable regulatory authorities, the time and cost to obtain regulatory approvals for our drug candidates may increase, delaying commercialization and harming our competitive position. Even if granted, expedited pathways may be subject to significant conditions, including restricted use, additional labeling requirements, and burdensome post-approval studies or risk management obligations, and changes in policies or requirements could further reduce or eliminate any expected benefit.

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

Regulatory requirements after we receive the regulatory approvals may include pharmacovigilance and adverse event reporting, manufacturing and quality controls, continued compliance with cGMP and GCP, labeling and promotional restrictions, recordkeeping, inspections, quality testing, and potentially costly post-marketing studies, and approvals may be limited to specific indications or subject to additional conditions. If previously unknown safety or quality issues arise, including issues relating to third-party manufacturers or manufacturing processes, or if we fail to comply with regulatory requirements, regulators may impose marketing or manufacturing restrictions, require product withdrawal or recalls, issue warning letters, place clinical trials on hold, refuse to approve pending applications or supplements, suspend or revoke approvals, refuse to accept our INDs or NDAs, seize or detain products or restrict import/export, and impose injunctions or civil, administrative or criminal penalties. In addition, changes in laws, regulations or policies, or government investigations and related negative publicity, could further delay or limit our activities, and any failure to maintain compliance could result in loss of approvals and materially harm our business operation and financial condition.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions.

Healthcare providers play a primary role in recommending and prescribing products, and if we obtain approval for any of our drug candidates and commercialize them in China, our sales, marketing and medical education activities may become subject to PRC fraud and abuse laws and heightened enforcement scrutiny, making compliance efforts costly and uncertain. Regulatory or law enforcement authorities may determine that our business practices, or those of third parties we work with, do not comply with applicable healthcare, fraud and abuse, anti-bribery or anti-corruption requirements, including PRC anti-bribery rules, the U.S. FCPA, and similar laws in other jurisdictions as we expand globally. If we or our counterparties are found noncompliant, we could face significant civil, criminal and administrative penalties, damages, disgorgement, fines, reputational harm, contractual liability, diminished profits, curtailment of operations, loss of export licenses, restrictions on doing business with governmental entities, denial of reimbursement, and/or exclusion from government-funded healthcare programs, any of which could materially adversely affect our business and results of operations.

We face regulation and potential liability related to privacy, data protection and information security.

We are subject to extensive and evolving local, state, national and international data protection and privacy laws, regulations, standards and contractual obligations across the jurisdictions where we operate and conduct trials. In case we do not fully satisfy all applicable requirements or prevent incidents such as unauthorized access, disclosure, leakage or misuse due to hacking, human error, employee misconduct or negligence, or system failures, we may face enforcement actions that would adversely affect our business operations. In addition, we rely on hospitals, CROs and other third-party partners, licensees, contractors and consultants, and any privacy or security failure by them may be attributed to us or perceived as our failure, which could undermine trust and expose us to investigations, enforcement actions, fines, potential imprisonment of company officials, public censure, private damages claims, reputational harm and loss of goodwill, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

We are subject to stringent data transfer and cybersecurity laws and policies.

We process data in our research, development, and clinical trial activities, including scientific data, personal information, important data, and potentially human genetic resources. As a result, we may be subject to stringent and evolving data privacy and cybersecurity laws and policies in the PRC and other jurisdictions. Key PRC regimes include the Measures for the Management of Scientific Data (科學數據管理辦法), the Administrative Regulations of PRC on Human Genetic Resources (中華人民共和國人類遺傳資源管理條例), the Biosecurity Law of the People's Republic of China (中華人民共和國生物安全法), the Cybersecurity Law of the People's Republic of China (中華人民共和國網絡安全法), the Data Security Law of the People's Republic of China (中華人民共和國數據安全法), the Personal Information Protection Law of the People's Republic of China (中

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華人民共和國個人信息保護法), the Measures for Cybersecurity Reviews (網絡安全審查辦法), the Regulations on Network Data Security Management (網絡數據安全管理條例), and outbound data transfer rules such as the Measures for the Security Assessment of Outbound Data Transfer (數據出境安全評估辦法), the Measures for the Standard Contractual for Outbound Cross-Border Transfer of Personal Information (個人信息出境標準合同辦法), and the Provisions on Facilitating and Regulating Cross-Border Data Flow (促進和規範數據跨境流動規定). For details, see “Regulatory Overview.” These requirements may restrict cross-border data transfers and may impose approvals, filings, security assessments, standard contract filings, or personal information protection certification. The scope, interpretation, and enforcement of these regimes remain uncertain and may tighten over time. If we cannot complete required procedures on a timely basis or at all, or if we are required to undergo cybersecurity or national security related review, we may face restrictions on data sharing, delays or disruptions to our R&D and international collaboration, increased compliance costs, required changes or suspension of certain operations, and administrative penalties such as fines. Any of these outcomes could materially and adversely affect our business, liquidity, and financial results.

If we or other business partners fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties and other negative consequences.

We and certain third parties we work with, such as our CROs, CDMO partners 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 generally contract with third parties for the disposal of these materials and wastes and we cannot guarantee our contractors could continuously maintain their qualifications with regard to such disposal. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages. 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. We may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

RISKS RELATING TO OUR OPERATIONS

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

Recruiting, retaining and motivating senior management, scientific, clinical and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, in particular our core R&D team members, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees may be difficult and may take an extended period of time. Competition to hire from limited pool of qualified and suitable talents is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms.

We may fail to effectively manage our anticipated growth or execute on our growth strategies.

Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. 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 teams that we may develop, successful hiring and training of personnel, as well as effective and efficient financial and management control and quality control. For details, see “Business – Our Strategies.” 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 may have a material and adverse effect on our business, financial condition, results of operations, and prospects.

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We may face risks in potential engagement in acquisitions or strategic partnerships.

To drive growth, we may pursue acquisitions or strategic partnerships in the future, which could increase our capital needs and dilute your [REDACTED] in our H Shares. Such transactions may also cause us to incur debt or assume contingent liabilities and could involve integration challenges, management distraction, loss of key personnel or relationships, counterparty and product uncertainties, significant one-time costs and future amortization, and accounting treatment changes that may affect our financial results. We may also be unable to identify suitable opportunities, which could limit our growth and access to important technologies or promising drug candidates.

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

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

Negative publicity may materially and adversely affect our reputation and business operations.

Our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. We may engage various third parties to facilitate our R&D activities, expand our commercialization network and increase market access for our drugs, which could 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 us, 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.

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

We plan to pursue overseas opportunities through local partnerships, licensing or co-development arrangements, and expanded global clinical programs. These activities may expose us to additional risks that could materially and adversely affect our ability to achieve or sustain profitable operations, including higher expenses and management distraction, political, cultural, economic, or regulatory changes in specific countries or regions, differing requirements for drug approval and commercialization, difficulties enforcing contracts in local jurisdictions, potentially weaker intellectual property protection, unexpected tariffs, trade barriers, or regulatory shifts, compliance burdens relating to tax, employment, immigration, and labor rules for personnel traveling abroad, and business interruptions arising from geopolitical events such as war or terrorism or from natural disasters. Any of these risks could materially and adversely affect our ability to generate and sustain revenue and profits from international markets.

Changes in U.S. and international trade policies and political tensions, particularly with regard to China, may adversely impact our business and results of operations.

Changes in U.S. and international trade policies and rising geopolitical tensions, particularly relating to China, including the imposition or increase of tariffs, trade barriers, capital controls, and tighter investment or technology transfer restrictions, could materially and adversely affect our business, financial condition, results of operations, cash flows, and prospects. Moreover, volatility in the global economic, political and financial environment, including fluctuations in interest rates due to monetary tightening or easing, inflation, currency and commodity price swings, reduced liquidity and weakened investor sentiment, could increase uncertainty and tighten or disrupt capital and credit markets, raise our funding costs and constrain financing availability, thereby materially and adversely affecting our business, financial condition, results of operations and prospects. These developments could disrupt or delay collaboration with suppliers, CROs, CDMO partners, and other counterparties, affect the import or export and delivery of materials, equipment, or samples used in drug development, increase sourcing, logistics, and compliance costs, constrain the cross-border

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hiring or deployment of scientific and clinical personnel, and slow international clinical collaboration and regulatory coordination, which could delay development timelines and reduce future market access or competitiveness in certain jurisdictions.

For example, on February 21, 2025, U.S. President Donald J. Trump issued a memo entitled the “America First Investment Policy” (the “**America First Memo**”), outlining the ongoing review and consideration of potential new or expanded restrictions on U.S. outbound investment in the PRC in sectors such as semiconductors, artificial intelligence, quantum, biotechnology, hypersonics, aerospace, advanced manufacturing, and directed energy. The America First Memo also contemplates potential restrictions on investments in publicly traded securities by pension funds, university endowments and other limited partner investors. Further, on April 15, 2025, the U.S. Department of Commerce announced investigations into the national security implications of semiconductor and pharmaceutical product imports. On December 18, 2025, the BIOSECURE Act was signed into law by the U.S. President. The core provisions of the enacted BIOSECURE Act stipulate that federal agencies are prohibited from contracting with or funding companies that are designated “biotechnology companies of concern.” The BIOSECURE Act’s final definition of “biotechnology companies of concern” includes (A) entities on the Department of Defense’s section 1260H list of Chinese military companies operating in the United States (known as the “1260H List”), and (B) entities that will be named through a process headed by the office of management and budget (“**OMB**”), who must supplement the list of biotechnology companies of concern within one year of enactment. If our suppliers or business partners were to be listed as “biotechnology companies of concern,” our 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. Prohibitions in the BIOSECURE Act will not take effect until the OMB issues implementing guidance and relevant federal regulations are finalized. The timing and substance of such enabling regulations remain subject to uncertainty and may differ materially from current expectations.

Furthermore, the U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. Any rising trade and political tensions or unfavorable government policies on international trade, such as capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. We cannot predict how tariff policies may further evolve or anticipate any potential impacts of subsequent developments in such policies on our business. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, and the demand for and competitiveness of our drugs. If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

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

Our operations may be under the threat of natural disasters, such as floods, typhoons, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, other factors beyond our control, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Any of the foregoing events and other events beyond our control could cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

We have limited insurance coverage.

We maintain industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. In line with general market practice, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Our insurance coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. If we were

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to incur any liability or suffer any loss that exceeds the scope or limits of our insurance coverage, we may be required to bear the uncovered portion of such losses, which could result in substantial financial costs and a diversion of management attention and resources.

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

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. We may be unable to prevent, detect or deter all such instances of misconduct by our employees or third parties. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business, results of operations and reputation.

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

Our information technology systems and those of our CROs, consultants, partners and other third-party service providers remain vulnerable to a range of threats, including computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, wars, and telecommunication and electrical failures. Any such event could lead to interruptions in our business operations and may result in a material disruption to our research and development activities. The use of unlicensed or pirated software, whether intentionally or inadvertently, may expose us to significant legal, operational and reputational risks. Moreover, the discovery of pirated software use may result in regulatory investigations, intellectual property infringement claims, fines or penalties, and could damage our relationships with partners, investors or regulators. To the extent that any disruption, data loss or security breach results in unauthorized access, disclosure or loss of confidential or proprietary information, we may be subject to legal liability, suffer reputational damage, and face delays in our research and development efforts.

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

Most of our assets are situated in the PRC and most of our Directors and officers reside in the PRC. Therefore, there remains the possibility that it may be difficult to effect service of process outside the PRC upon most of our directors and officers, including with respect to matters arising under applicable securities laws. The PRC does not have treaties providing for the reciprocal recognition and enforcement of civil case judgments of courts with the U.S. and many other countries. Consequently, you may experience difficulties in enforcing against us or our directors or officers in the PRC any judgments obtained from courts outside of the PRC.

RISKS RELATING TO THE [REDACTED]

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

Prior to the completion of the [REDACTED], there has been no [REDACTED] for our H Shares. There can be no guarantee that an active [REDACTED] for our H Shares will develop or be sustained after completion of the [REDACTED]. The [REDACTED] of our H Shares may drop below the [REDACTED] at any time after completion of the [REDACTED]. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the H Shares will not decline following the [REDACTED]. The [REDACTED] and [REDACTED] of our H Shares may be [REDACTED] and could fluctuate widely in response to factors beyond our control, including general market conditions of the securities markets in Hong Kong, Chinese Mainland, the U.S. and elsewhere in the world. In addition to market and industry factors, the [REDACTED] and [REDACTED] for our H Shares may be highly [REDACTED] for specific business reasons. In particular, factors such as variations in our revenue and earnings, if any, and cash flow could cause the [REDACTED] of our H Shares to change substantially. Any of these factors may result in large and sudden change in the [REDACTED] and [REDACTED] of our H Shares.

RISK FACTORS

Future [REDACTED] or perceived [REDACTED] of substantial amounts of our H Shares in the [REDACTED] could have a material and adverse effect on the [REDACTED] of our H Shares and our ability to raise additional capital in the future.

Future [REDACTED] of a significant number of our H Shares by any existing Shareholder in the [REDACTED] after the [REDACTED], or the perception that these [REDACTED] could occur, could cause the [REDACTED] of our H Shares to decline and could materially impair our future ability to raise capital through [REDACTED] of our H Shares. We cannot predict and assure you that any existing Shareholder will not [REDACTED] of any H Shares they may own now or in the future. The effect of such disposal, if any, on the [REDACTED] of the H Shares cannot be predicted. In addition, while [REDACTED] shares in the [REDACTED] are not subject to any restrictions on the [REDACTED] of the H Shares they [REDACTED], except as disclosed in this document, they may have existing arrangements or agreement to [REDACTED] of part or all of the H Shares they hold either immediately or within certain period upon the completion of the [REDACTED] for legal and regulatory, business and market, or other factors. Any [REDACTED] of the H Shares [REDACTED] by such [REDACTED] pursuant to such arrangement or agreement could adversely affect the [REDACTED] of our H Shares and any sizeable sale could have a material adverse effect on the [REDACTED] of our H Shares and could cause substantial [REDACTED] in the [REDACTED] of our H Shares.

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

Our Single Largest Shareholder has substantial influence over our business, including matters relating to our management, policies and decisions regarding acquisitions, mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of directors and other significant corporate actions. Immediately after completion of the [REDACTED], assuming the [REDACTED] is not exercised and based on the [REDACTED] of HK\$[REDACTED], being the mid-point of the indicative [REDACTED] range, our Single Largest Shareholder will hold (including direct and indirect shareholdings) approximately [REDACTED]% of the issued share capital in our Company. In addition, the interests of our Single Largest Shareholder may differ from the interests of other Shareholders.

You will incur immediate and significant [REDACTED] and may experience further [REDACTED] in the future.

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

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

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we have not yet adopted a dividend policy with respect to future dividends. Therefore, you should not rely on an [REDACTED] in our H Shares as a source for any future dividend income. Our Board has discretion as to whether to distribute dividends, subject to certain restrictions under PRC laws and regulations, namely that our Company may pay dividends out of profits or share premium, provided always that in no circumstances may a dividend be paid out of share premium if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our Board. The return on your [REDACTED] in our H Shares will likely depend entirely upon any future price appreciation of our H Shares. There is no guarantee that our H Shares will appreciate in value or even maintain the [REDACTED] at which you [REDACTED] the H Shares. You may not realize a return on your [REDACTED] in our H Shares and you may even lose your entire [REDACTED] in our H Shares.

RISK FACTORS

We may allocate the [REDACTED] from this [REDACTED] in ways that you and other Shareholders may not agree.

Our management will have broad discretion in the application of the [REDACTED] from this [REDACTED], including for any of the purposes described in the section titled “Future Plans and [REDACTED].” Because of the number and variability of factors that will determine our [REDACTED] from this [REDACTED], their ultimate use may vary substantially from their currently intended use. Our management might not apply the [REDACTED] in ways that ultimately increase the value of your [REDACTED], and the failure by our management to apply these [REDACTED] effectively could harm our business.

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

This document contains certain statements and information that are forward-looking and uses forward-looking terminology such as “aim,” “anticipate,” “aspire,” “believe,” “could,” “expect,” “going forward,” “intend,” “may,” “ought to,” “plan,” “project,” “schedule,” “seek,” “should,” “target,” “vision,” “will,” “would,” and the negative of these words and other similar expressions. These statements are, by their nature, subject to significant risks and uncertainties. Prospective [REDACTED] are cautioned that reliance on any forward-looking statement involves risk and uncertainties and that, even if the Directors believe the assumptions related to those forward-looking statements are reasonable, any or all of those assumptions could prove to be inaccurate and, as a result, the forward-looking statements based on those assumptions could also be incorrect.

The information and statistics from official government sources and the industry report have not been independently verified.

The information and statistics from official government sources have not been independently verified by us, the Sole Sponsor, and the other [REDACTED], any of our or their respective directors, officers or representatives or any other party, other than Frost & Sullivan, involved in the [REDACTED]. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate. You should therefore not place undue reliance on such information.

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