

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. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biopharmaceutical industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our H Shares. The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] of our H Shares could decline, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-looking Statements” in this Document. You should seek professional advice from your relevant advisors regarding your prospective [REDACTED] in the context of your particular circumstances.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to the development, clinical trials and regulatory approval of our drug candidates, (ii) risks relating to manufacturing and commercialization of our drug candidates; (iii) risk relating to our financial position and need for additional funding; (iv) risks relating to our intellectual property rights; (v) risks relating to our business and industry, (vi) risks relating to doing business in jurisdictions where we operate and (vii) risks relating to the [REDACTED]. Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also have a material adverse effect on our business, financial condition, results of operations and prospects. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

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

Our business and financial prospects depend substantially on the success of our drug candidates. If we are not able to successfully complete clinical development, obtain regulatory approval and commercialize our drug candidates, including our Core Products, or experience delays in doing so, our business prospects could be adversely affected.

The biopharmaceutical industry is highly competitive and subject to rapid technological change. We will face significant competition with respect to any drug candidate that we develop or seek to commercialize. Many of our drug candidates will face competition from existing therapies or new drugs in development by major international and domestic pharmaceutical companies targeting the same indications or biological targets. For example, our Core Product DNV3 (an anti-LAG-3 TCM) may face competition from other LAG-3-targeting therapies being developed globally, as well as from established immuno-oncology treatments; and our Core Product SMET12 (an EGFR×CD3 TCE) may face competition from other TCE therapies with the same or similar targets as well as from EGFR-targeting therapies more broadly. If our competitors develop therapies that are more effective, safer, or reach the market faster than our drug candidates, or if they achieve better market acceptance, our ability to commercialize our drug candidates successfully could be significantly hindered. This intense competition could materially and adversely affect our financial condition, results of operations and business prospects.

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For the next few years, our financial condition and results of operations will be significantly dependent on obtaining regulatory approvals for, and successfully commercializing, DNV3, SMET12, CMD011, CMDE005 and other drug candidates. If we are unable to successfully obtain the required regulatory approvals, achieve commercialization or complete the clinical development of any of our major drug candidates in a timely manner, or if we experience significant delays or cost overruns in doing so, our business, financial condition, results of operations and prospects would be materially and adversely affected.

Clinical development of biopharmaceutical products is risky, time-consuming and inherently uncertain, and our drug candidates may fail to demonstrate the safety and efficacy required for regulatory approval.

We may experience numerous unforeseen events during clinical trials that could delay or prevent our ability to obtain regulatory approval or commercialize our drug candidates. For example, regulators may not authorize the commencement of a trial or may put a trial on hold; our clinical trials could produce negative or inconclusive results, requiring us to conduct additional trials or abandon projects; enrollment of patients may be slower than expected or patients may drop out at higher rates than anticipated; and we might have to suspend or terminate trials due to safety issues or failure to meet endpoints. We could also face higher than expected costs or supply shortages that disrupt our trials. If any of these events occur, we may be unable to commercialize our drug candidates at all, which would materially harm our business and prevent us from generating sufficient revenues or cash flow to continue operations.

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

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy in humans. If the results of clinical trials of our drug candidates are not positive or only modestly positive for the proposed indications, or if they raise safety concerns, any or some of the following could occur: regulatory approvals for our drug candidates would be delayed or denied; we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan; we may be required to add labeling statements, such as a "boxed" warning or a contraindication; we may be required to create a medication guide outlining the risks of the adverse effects for distribution to patients; we may be required to implement a risk evaluation and mitigation strategy program, including medication guides, doctor communication plans and other risk management tools with restricted distribution methods and patient registries; we may not be able to obtain regulatory approvals for all the proposed indications as intended; we may be subject to restrictions on how the drug is distributed or used; we may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates; we may be unable to obtain reimbursement for the use of the drug; or conditional regulatory approval of our drug candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.

If our drug candidates ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, our business, financial condition, results of operations and prospects would be materially and adversely affected.

Our drug candidates may cause undesirable adverse events.

Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or in the delay or denial of regulatory approval by the regulatory authorities. There is a risk that ongoing

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or future clinical trials may identify unforeseen adverse effects or more severe side effects. These potential risks could affect the broader clinical applicability of our drug candidates and their use in combination therapies. In such an event, our clinical trials could be suspended or terminated and the regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications.

Drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial and could result in potential product liability claims. Additionally, if one or more of our drug candidates ultimately receives regulatory approval and undesirable side effects are subsequently identified, several potentially significant negative consequences could result, including: we may suspend marketing of the drug; regulatory authorities may withdraw approvals of the drug; regulatory authorities may require additional warnings on the label; we may be required to develop risk evaluation and mitigation measures for the drug or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under such programs; and we may be required to conduct post-market studies.

Negative results from off-label drug use of our drug candidates could negatively impact our business, financial condition, results of operations and prospects and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use beyond our control. Off-label drug use refers to prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Once approved, our products may be used for purposes beyond their labeled indications, such as treatment of other conditions for which we are conducting or may conduct exploratory studies. For example, as of the Latest Practicable Date, DNV3 was being developed for advanced/metastatic solid tumors and lymphomas, and locally advanced unresectable or metastatic melanoma and SMET12 was being developed for EGFR-positive advanced solid tumors, both of which may in the future be investigated or prescribed for other indications beyond those covered by regulatory approvals.

There is a risk that our drug candidates, upon regulatory approval for certain indications, may be subject to off-label drug use with indications, dosages or dosage forms not approved by relevant authorities. Similar to other innovative therapies in our therapeutic areas, reported clinical practice may involve off-label use, and the occurrence of such off-label use could render our drug candidates less effective or entirely ineffective for those indications, or cause unexpected adverse events, particularly if used at inappropriate dosage levels.

Any such occurrences could create negative publicity and significantly harm our business reputation, product brand name, commercialization efforts and financial condition. These occurrences may also expose us to liability arising from off-label use of our drug candidates upon regulatory approval, which may subsequently cause, or lead to, delays in our ongoing or planned clinical trials and may also ultimately result in failure to obtain or maintain regulatory approval.

Results of earlier clinical trials of our drug candidates may not be predictive of results of later-stage clinical trials.

Drug candidates in later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial and early phase trials. Numerous companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. For example, first-generation EGFR targeting monospecific antibodies, such as cetuximab and panitumumab, had been investigated in the treatment of ESCC and TNBC. Although certain studies demonstrated preliminary anti-tumor activity, these antibodies generally failed to show significant survival benefits for the two indications. Future clinical trial results of our drug candidates may not be favorable for various reasons, and ultimately we may not be able to successfully develop and commercialize them.

In some cases, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to changes in trial procedures set forth in protocols, differences in the size and type of the patient populations (such as genetic differences), patient

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adherence to the dosing regimen and other trial protocols, and the rate of dropout among clinical trial participants. As our drug candidates progress from preclinical to early- to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered in an effort to optimize processes and results. Such changes carry the risk that they may not achieve these intended objectives.

In the case of any trials we conduct, results may also differ from earlier trials due to the larger number of clinical trial sites, involvement of additional countries and languages, and other logistical complexities. Any of these changes could make the results of planned clinical trials or other future trials less predictable, could cause our drug candidates to perform differently than expected, and could delay completion of clinical trials, delay approval of our drug candidates, and/or jeopardize our ability to commence commercialization.

Development of product candidates in combination with other therapies could expose us to additional risks.

In addition to monotherapies, we are developing certain pipeline products with other commercialized products as combination therapies to achieve potential synergistic effects and improved efficacy profile. For instance, we are investigating the safety and efficacy of our Core Product, DNV3, in combination with toripalimab, an approved anti-PD-1 antibody drug, in China. However, development of any of our product candidates in combination with one or more other therapies could expose us to additional risks. For instance, supply issues for such commercialized products may arise during our clinical development, which may lead to delay or suspension of our clinical trials for the combination therapy. Also, we may be unable to successfully develop or market our pipeline products or may experience significant regulatory delays, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates. Additionally, as combination therapies may increase the rate of serious or unexpected AEs, which could result in a clinical hold as well as pre-approval and post-approval restrictions by the regulatory authorities on the proposed combination therapy, including narrowing of the indication, warnings, additional safety data collection and monitoring procedures, even if the cause of such serious or unexpected AEs is not directly attributed to our product candidate. Any of these events or restrictions could have a material adverse effect on our business, delay our regulatory approval, and decrease the market acceptance and profitability of our product candidate if approved for a combination therapy.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients or participants who remain in the trial until their conclusion. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients or participants to participate in these trials, or if there are delays in the enrollment of eligible patients or participants as a result of the competitive clinical enrollment environment. We may experience difficulties in patient enrollment in our clinical trials due to many factors: design and eligibility criteria for the clinical trial in question; perceived risks and benefits of the drug candidate under study; our resources to facilitate timely enrollment in clinical trials; patient referral practices of physicians; availability of competing therapies also undergoing clinical trials; our investigators' or clinical trial sites' efforts to screen and recruit eligible patients or participants; or proximity and availability of clinical trial sites for prospective patients or participants. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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

As we have limited financial and managerial resources, we focus our product pipeline on research programs and drug candidates that we identify for selected indications and prioritize those that we believe have greater clinical potential and strategic importance. As a result, we may forgo or delay the pursuit of opportunities with other drug candidates or indications that may later prove to have greater commercial potential or a higher likelihood of regulatory approval. Our spending on current and future R&D programs and drug candidates for selected indications may not yield any commercially viable products. Furthermore, if we do not accurately evaluate the clinical value, competitive landscape or market potential for a particular drug candidate, we may relinquish valuable rights to such candidate through out-licensing, co-development or collaboration arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate or indication in a therapeutic area where it would have been more advantageous to pursue a partnering arrangement.

The regulatory approval processes of the NMPA, FDA and other comparable regulatory authorities depend on numerous factors, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The regulatory approval processes of regulatory authorities depend on factors that may be outside our control. Generally, such approvals take years to obtain following the commencement of preclinical studies and clinical trials. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change in the future during the course of development and may vary among jurisdictions.

We cannot guarantee that we will be able to obtain regulatory approvals for our drug candidates we may discover, in-license or acquire and seek to develop in the future. Our drug candidates could fail to receive regulatory approval for many reasons, including: disagreement with the design or implementation of our clinical trials; failure to demonstrate that a drug candidate is safe, effective and potent for its proposed indication; failure of our clinical trial results to meet the level of statistical significance required for approval; failure of our clinical trial process to pass relevant GCP inspections; disagreement with our interpretation of data from preclinical studies or clinical trials; insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of an NDA or other applications to obtain regulatory approval; failure of the manufacturer of our drug candidates to pass GMP inspections during the regulatory review process or across the production cycle; and failure of our clinical trial sites to pass audits carried out by the NMPA, FDA or other regulatory authorities.

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 third parties on our ongoing preclinical and clinical programs. For example, we rely on contract research organizations ("CROs"), clinical trial sites, consultants and other third parties to monitor, support and/or conduct preclinical studies and clinical trials of our drug candidates. We work with these parties to execute our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities.

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If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Except for remedies available under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs fail to duly perform their contractual obligations or meet expected deadlines, if they need to be replaced or if the conduct or accuracy of the clinical data by them or our clinical investigators is questioned by regulatory authorities due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for, or successfully commercialize, our drug candidates. Switching or adding additional CROs involves additional cost and delays, which can materially and adversely affect our ability to meet our desired clinical development timelines. Any of the foregoing events may cause cost increases, restrict our ability to generate revenue and have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our relationships with principal investigators (“PIs”), key opinion leaders (“KOLs”), physicians and experts play an important role in our R&D and future commercialization of our drug candidates. We have established interaction channels with PIs, KOLs, physicians and experts to gain first-hand knowledge of clinical needs and clinical practice trends, which is critical to our ability to develop innovative and market-responsive therapies. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with our PIs, KOLs, physicians and experts, or that our efforts to maintain or strengthen such relationships will yield the successful development and commercialization of our drug candidates.

Industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or instead cooperate with our competitors. Also, their insights and perceptions, which we consider in our R&D process, may be inaccurate and lead us to develop products without significant market potential. Moreover, we cannot assure you that our academic collaborations or scientific promotion activities will continue to serve as an effective development or marketing strategy.

Industry participants may no longer want to collaborate with us, attend our scientific conferences, or participate in our clinical trials, and our marketing or collaboration strategy may no longer be able to yield results that are commensurate to our efforts spent. If we are unable to develop our drug candidates or generate returns from our relationships with industry participants as anticipated, our business, financial condition, results of operations and prospects may be materially and adversely affected.

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

All jurisdictions in which we intend to conduct our biopharmaceutical activities strictly regulate the research, development, approval, manufacturing, marketing, sales and distribution of pharmaceutical products. These jurisdictions employ extensive regulatory requirements at each stage of the product life cycle, and differences in regulatory regimes across jurisdictions may lead to a higher compliance burden for us. The process of obtaining regulatory approvals and maintaining compliance with applicable laws and regulations requires significant time and financial resources.

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

We may fail to identify drug candidates for clinical development for a number of reasons. For example, our research methodology may be unsuccessful in identifying potential drug candidates with desirable safety and efficacy profiles, or those we identify may later be shown to have unfavorable pharmacological properties or manufacturing challenges that make them unmarketable or unlikely to receive regulatory approval. We cannot guarantee that we will be successful in identifying new drug candidates with sufficient clinical potential.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results suitable for further development due to: the research methodology used may not be successful in identifying potential indications and/or drug candidates; potential drug candidates may, after further study, be shown to have limited efficacy, unexpected toxicities or unfavorable pharmacokinetic characteristics that indicate they are unlikely to be effective drugs; or it may take greater time, effort and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

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

The biopharmaceutical industry is rapidly evolving, requiring continuous innovation and significant resources. We cannot assure you that we will successfully adapt to new technologies, bring new or enhanced products to market, or obtain sufficient intellectual property protection in a timely manner. Failure to do so may render our past efforts obsolete, reduce the competitiveness of our drug candidates, and adversely affect our business, financial condition and prospects.

RISKS RELATING TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

We have no experience in manufacturing biopharmaceutical products on a commercial scale, and currently lack in-house manufacturing facilities; if we encounter difficulties in the production of our drug candidates, our development and commercialization efforts could be adversely affected.

As of the Latest Practicable Date, we do not operate our own manufacturing plant for commercial production, and we rely on third-party contract development and manufacturing organizations ("CDMOs") to produce our drug candidates. We have not yet manufactured any of our drug candidates at large scale for commercial use, and we have limited experience with the complex process of biologics manufacturing. Process development or scale-up challenges may arise as we progress from laboratory-scale to commercial-scale production. Manufacturing methods and formulations may need to be modified or optimized during development, and such changes carry the risk that the altered process will not achieve the intended results.

We could encounter issues meeting the strict quality standards and specifications required by regulators like the NMPA or FDA on a consistent basis, or experience shortages of raw materials, equipment malfunctions, or other disruptions. Any problems in scaling up production or maintaining product quality could delay our clinical trials, increase costs, result in product shortages, or impair our ability to supply the market upon approval. In severe cases, manufacturing setbacks could require us to delay or suspend development of the affected product, which would materially and adversely impact our business.

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We intend to work with third parties for the commercialization of our drug candidates. We may fail to identify competent third parties for such purposes, fail to achieve the expected synergies with the clinical development partners, and have little or no control over the marketing and sales efforts of the commercialization partners.

We may pursue collaborative arrangements regarding sales and marketing of our drug candidates in China and overseas. As of the Latest Practicable Date, we had not entered into any commercialization arrangement for our drug candidates. As we seek to establish these collaborations, we may face challenges in identifying capable third-party partners who can support commercialization. Even if we are able to establish such relationships, we may have limited control over their marketing and sales efforts, which could impact our ability to achieve expected revenue. Additionally, we cannot guarantee that we will be able to establish or maintain collaborations with third parties within the desired timeframe, or at all, which could delay or prevent the commercialization of our drug candidates and the generation of product revenue.

We may not achieve the expected revenue and cost synergies from such collaborations. These synergies are subject to significant competitive and economic uncertainties and may not materialize within the anticipated timeframe. Moreover, synergies from collaboration may be offset by additional costs, increases in other expenses, operating losses, or other problems unrelated to the collaboration. Disputes may also arise between us and our collaboration partners. Such disputes may cause delay or termination of commercialization of our drug candidates after their market launch or may result in costly litigation or arbitration that diverts management attention and resources. As a result, there can be no assurance that the synergies expected from these collaborations will be achieved.

We rely on third-party manufacturers for the supply of our drug candidates, and problems with, or loss of, these external suppliers could disrupt our operations.

For manufacturing of our product candidates, we currently outsource such production to a limited number of highly reputable CDMOs. If our CDMO partners encounter production difficulties, such as capacity constraints, raw material supply interruptions, or quality control issues, it could lead to delays in our clinical development or future product launches. For instance, any failure by our CDMO partners to deliver sufficient quantities of our drug candidates meeting required quality standards on schedule could slow down or derail our clinical trials or commercialization efforts. Reliance on third-party manufacturers means we have limited control over the production process and timelines. If we need to switch manufacturers or engage additional suppliers, we may face difficulties in identifying alternatives with the necessary capabilities, and technology transfer to a new manufacturer could be time-consuming and costly. Any significant disruption in our supply chain or need to find replacement manufacturers could result in delays, higher costs or an inability to meet demand for our products.

The market size of our drug candidates might be smaller than we expected.

Our estimates regarding eligible patient populations, pricing and available coverage and reimbursement determine our estimated market size, which may differ significantly from the actual market addressable by our drug candidates. These estimates, based on patient foundations, market research and other sources, may prove to be inaccurate. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. As a result, the number of patients who may benefit from our drug candidates may be lower than expected, and the overall addressable patient population may be more limited.

For example, our Core Product DNV3 has been developed for the treatment of advanced/metastatic solid tumors and lymphomas. However, given the presence of existing or potential treatment options, the market potential of DNV3 may be limited. As a result, the actual

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addressable patients for DNV3 could be smaller than expected. Similarly, the addressable market size for our other drug candidates may be constrained competing therapies, the lower prevalence of the relevant diseases, and patient access to diagnosis and treatment.

Our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

Our products may fail to gain sufficient market acceptance by physicians, patients, third-party payers and other relevant parties in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from our portfolio and may not become profitable.

The degree of market acceptance of our drug candidates will depend on many factors, including: the clinical indications for which our drug candidates are approved; physicians’ and patients’ perception of our drug candidates as safe and effective treatments; the potential and perceived advantages of our drug candidates over alternative treatments; the prevalence and severity of side effects; labeling or product insert requirements of the NMPA, FDA or other applicable regulatory authorities; limitations or warnings contained in approved labeling; the timing of market introduction of our drug candidates as compared with competing drugs; the cost of treatment in relation to alternative therapies; inclusion in the National Reimbursement Drug List (“NRDL”) or other government-sponsored medical insurance programs, or reimbursement by third-party payers; patients’ willingness to pay out-of-pocket in the absence of such coverage; the relative convenience and ease of administration compared to alternatives; and the effectiveness of our sales and marketing efforts.

Even if we achieve initial acceptance, we may be unable to maintain it over time if new products or technologies are introduced that are more favorably received, more cost-effective, or render our products obsolete.

Our drug candidates may not be covered by reimbursement programs or may become subject to unfavorable reimbursement practices, either of which could harm our business.

The successful commercialization of our drug candidates will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities and/or third-party payers, such as private health insurers and health maintenance organizations. The regulations that govern reimbursement for new therapeutic drugs vary substantially from country to country.

In China, the NRDL and Provincial Reimbursement Drug Lists (“PRDLs”) include drugs under the National Medical Insurance Catalogue, which affect the amounts reimbursable to program participants. There can be no assurance that any of our drug candidates will be included in the NRDL or PRDLs after initial approval for commercialization. If we fail to have our drug candidates included, our commercial revenues would rely heavily on patient self-payment, which could make our products less competitive.

A key trend in the global pharmaceutical industry is cost containment. Government authorities and third-party payers have increasingly sought to limit coverage and reimbursement amounts for particular medications. Our net revenue from sales may decrease as a result of price reductions required for inclusion in the NRDL or PRDL, or future policies imposing deeper-than-expected price cuts. Third-party payers may also require us to provide predetermined discounts or challenge the prices charged for our products.

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We cannot assure you that reimbursement will be available for our drug candidates, or that the level of reimbursement will be sufficient to support their successful commercialization. Reimbursement may impact demand for our drug candidates, as the higher costs associated with drugs administered under physician supervision may reduce uptake. If reimbursement is not available, or only at limited levels, we may not be able to commercialize our drug candidates effectively.

There may also be significant delays in obtaining reimbursement coverage. Reimbursement may be limited to the approved indications of the drug candidates by the NMPA, FDA or comparable authorities. Moreover, reimbursement does not imply that all costs will be covered, as patients may be required to bear a portion of expenses such as administration, distribution or supportive care. Net prices for drugs may also be adversely impacted by policies weakening IP protection, parallel imports, or government-mandated price negotiations.

RISK RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL FUNDING

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

We have devoted substantial financial resources to R&D of our drug candidates and have not generated any revenue from product sales to date. As a result, we have incurred net losses in each period since our founding. In particular, our net losses were RMB59.9 million and RMB81.0 million in 2024 and 2025, respectively, and we expect to continue to record significant operating losses in the near term. Investment in biopharmaceutical product development is highly speculative, requires large upfront expenditures, and carries a high risk of failure. We anticipate that our expenses will continue to increase as we advance clinical trials, seek regulatory approvals, build commercial capabilities, and expand our pipeline. These expenditures may not result in commercially successful products.

If any of our drug candidates fails in clinical development or does not gain regulatory approval or market acceptance, we may never achieve profitability. Moreover, even if we attain profitability in the future, we may not be able to sustain it. A failure to become and remain profitable could decrease our value, restrict our ability to raise additional capital or continue our R&D programs, and ultimately could lead to our business failure, in which case you may lose substantially all of your [REDACTED] in us.

We will need substantial additional capital to fund our operations, and if we fail to obtain sufficient funds on acceptable terms when needed, our business could suffer.

Developing biopharmaceutical products to approval and commercialization requires significant capital outlays over many years. We expect that we will seek further equity financing and possibly other sources of funding to support our ongoing trials, product launch preparations and other operating requirements. Our future funding needs will depend on many factors, including the progress and results of our clinical programs, the timing of regulatory approvals, the cost of building manufacturing and commercial infrastructure, and the evolution of the competitive and regulatory landscape. There is no assurance that additional financing will be available to us when required, or that it can be obtained on commercially reasonable terms. If we are unable to raise enough capital or must do so on terms that are overly dilutive or burdensome, we may have to delay, scale back or eliminate certain R&D projects or future commercialization plans. Insufficient funding could thus jeopardize our growth and could materially and adversely affect our business, financial condition, results of operations and prospects.

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We had net operating cash outflows during the Track Record Period and expect to continue to incur significant cash outflows in the foreseeable future.

Since our inception, our operations have consumed substantial amounts of cash. We had net cash used in operating activities of RMB53.4 million and RMB50.5 million in 2024 and 2025, respectively. We also face credit risk on the cash and cash equivalents deposited with financial institutions. If any of these institutions becomes insolvent and is taken into receivership by the relevant government agencies, there will be uncertainty as to the timing and extent to which we can recover our deposits.

We expect to continue experiencing net cash outflows from operating activities in the foreseeable future. We may need to obtain substantial additional funding to support the ongoing development of our drug candidates and our commercialization efforts, through [REDACTED] or private equity offerings, debt financing, collaborations or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on reasonable terms, we may be required to delay, limit, reduce or terminate our R&D programs or commercialization efforts.

We may incur impairment losses for prepayments and other receivables.

Our prepayments and other receivables primarily consist of prepayments to suppliers, deposits and other amounts due from third parties. However, there is no assurance that suppliers and service providers will perform their obligations in a timely manner, and we are exposed to credit risk in relation to such prepayments and receivables.

The assessment of impairment losses involves significant management judgment and estimation of key assumptions, and adverse changes in circumstances may result in decreases in the value of our prepayments and other receivables. We cannot assure you that such assumptions and estimates will not lead to material adjustments to the carrying amounts of our prepayments and other receivables in the future. Any significant impairment losses of prepayments and other receivables could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have not generated any revenue from the sales of drug products, and our ability to generate revenue and achieve profitability depends significantly on the successful development and commercialization of our drug candidates.

We currently have no drug products approved for commercial sale, have not generated any revenue from drug product sales, and do not anticipate generating any such revenue until after obtaining the requisite regulatory approvals. Our ability to generate revenue and achieve profitability depends on many factors, including: completing nonclinical and clinical development of our drug candidates; obtaining regulatory approvals and marketing authorizations; developing a sustainable and scalable manufacturing process, including establishing commercially viable supply relationships with third parties and/or building our own manufacturing capabilities; successfully launching and commercializing our drug candidates; addressing competing technological and market developments; identifying, acquiring and/or developing new drug candidates, intellectual property and technologies; negotiating favorable terms in collaborations, licensing, or other arrangements; maintaining, protecting, and enforcing our portfolio of intellectual property rights; and attracting, hiring and retaining qualified personnel.

Even if one or more of our drug candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercialization. Our expenses could exceed expectations if regulators require us to change our manufacturing processes, perform additional studies, or comply with new standards.

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Our revenue will also depend on the size of the market for the approved indication, the price of the product, the scope of coverage by reimbursement programs, and the willingness of patients to pay out-of-pocket. If the approved indication is narrower than expected, or if competition, clinical guidelines or physician choice reduces the addressable patient pool, we may not be able to generate significant revenue from sales of our drug candidates.

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

During the Track Record Period, we financed our operations, including R&D activities, through bank loans and equity financing. As of December 31, 2024 and 2025, our interest-bearing borrowings were RMB31.0 million and RMB20.0 million, respectively. We expect to continue incurring significant cash requirements to support the development of our drug candidates, and upon commercialization, to fund working capital and operating expenses.

We may need to obtain substantial additional capital to meet our ongoing operating and capital requirements, especially to fund our R&D activities, regulatory submissions, commercialization of drug candidates, and manufacturing capabilities. Our future funding requirements will depend on many factors, including: the progress, timing, scope and costs of our clinical trials, including the ability to enroll patients; the outcome, timing and cost of regulatory approvals; the progress and scope of discovery and early-stage development of new drug candidates; the preparation for anticipated commercialization of drug candidates and related product launches; the manufacturing requirements and scale-up for clinical and commercial supply; the amount and timing of milestone and royalty payments payable to or from collaborators; the cost of filing, prosecuting, defending and enforcing intellectual property rights; the cash requirements of any in-licensed drug candidates or acquisitions; and the expansion of our workforce and related expenses.

We may seek additional funding through equity offerings, debt financings, licensing and collaboration arrangements, or other sources. Such funding may not be available on terms favorable to us, or at all. Any equity financing could dilute the interests of our shareholders, while debt financing could increase our repayment obligations and subject us to restrictive covenants, including limitations on incurring additional debt, licensing intellectual property, or entering into other transactions.

Our ability to raise funds will also depend on prevailing market conditions and factors beyond our control. If adequate funds are not available, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, R&D activities or commercialization efforts for our drug candidates.

If we enter into collaboration or licensing arrangements to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to third parties our rights to technologies or drug candidates that we would otherwise seek to develop or commercialize independently or reserve for future collaborations.

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 such as wealth management products and structured deposits issued by banks. Pursuant to the relevant regulations promulgated by China Banking and Insurance Regulatory Commission (the predecessor of National Financial Regulatory Administration), financial institutions selling wealth management products cannot guarantee the returns of principal or interest of such products. As a result, our investments in these products are not guaranteed and are measured at fair value through profit or loss. Accordingly, any changes in their fair value are recorded as fair value gains or losses, which may directly affect our financial results.

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We may continue to invest in financial products in the future when we have surplus cash on hand and consider such investments stable and attractive. However, we cannot assure you that we will not experience losses arising from these investments, or that such losses will not have a material adverse effect on our financial condition and results of operations. In addition, the fair value of such investments is determined by applying certain valuation methodologies, which involve various assumptions and uncertainties. Any change in these assumptions may lead to different valuation results and, in turn, changes in the fair value of these financial assets at FVTPL, which could adversely affect our financial results.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our drug candidates and our technology platforms, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

As of the Latest Practicable Date, we held 21 patents and five patent applications in connection with our product candidates, including four patents related to DNV3, and eleven patents and one patent application related to SMET12, in China, the U.S. and EU. We cannot be certain that patents will be issued or granted with respect to our pending applications, or that issued or granted patents will not later be found to be invalid or unenforceable, or interpreted in a manner that does not adequately protect our drug candidates, or otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. Patent applications we have applied for may not be granted in the end. As such, we do not know the degree of future protection that we will have on our drugs and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our drug candidates could have a material adverse impact on our business.

The scope of patent protection in various jurisdictions is uncertain. Changes in either the patent laws or their interpretation may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any future granted patents will provide sufficient protection from competitors.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Our patent applications may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biopharmaceutical companies has been a common subject of litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Our drug discovery and development efforts involve significant risks of intellectual property disputes, and third parties may allege that we are infringing on their patents or other proprietary rights.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future drug candidates may be claimed to infringe upon the intellectual property rights of others. If any third party asserts that our products, processes or technologies violate their patents, trade secrets or other IP rights, we would likely have to dedicate significant time and resources to defend against such claims. Patent litigation and other intellectual property proceedings can be protracted, expensive, and unpredictable. They could force us to divert management attention and incur substantial legal costs. If we were found to infringe a valid patent

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of another party, we could be required to pay significant damages or license fees, and potentially be enjoined from further developing, manufacturing or selling the affected product. We might also need to seek a license to the third-party’s intellectual property, which may not be available on reasonable terms, or at all.

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.

We rely on patent rights and other forms of intellectual property protection for our drug candidates. To obtain and maintain such patent rights, we are required to pay maintenance fees, renewal fees, annuity fees and various other governmental fees in multiple jurisdictions, including the China National Intellectual Property Administration (“CNIPA”), the United States Patent and Trademark Office (“USPTO”) and other comparable agencies. These agencies impose numerous procedural, documentary, and compliance obligations throughout the lifetime of a patent or patent application.

In some cases, non-compliance may result in the abandonment or lapse of our patents or patent applications, or the loss of priority, which could lead to partial or complete loss of patent protection in the relevant jurisdiction. Such events may occur, for example, if we fail to respond to official actions within prescribed deadlines, fail to properly submit required documents, or fail to make timely fee payments. If any of our patents or patent applications covering our drug candidates were to lapse, be abandoned or otherwise be invalidated, our ability to protect our innovations would be materially compromised. This could enable competitors or third parties to gain access to our proprietary technologies, enter the market with similar products.

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

We rely on patent protection for our drug candidates, including our Core Products. However, patent rights differ across jurisdictions and may be weak, unavailable or subject to challenge, invalidation or circumvention. In markets where we lack adequate protection, competitors may develop or commercialize competing products, or export infringing products into our target markets. Defending our rights globally could be costly and uncertain, and failure to do so may adversely affect our business, financial condition, results of operations and prospects.

We may from time to time be involved in lawsuits to protect or enforce our intellectual property rights, which could be costly, time-consuming and uncertain, and could delay the development or commercialization of our drug candidates.

Litigation relating to patents and other intellectual property rights is common in the biopharmaceutical industry and inherently uncertain. Any such proceedings may result in substantial legal costs, reputational harm, and diversion of management and employee resources. Moreover, discovery procedures may require disclosure of our confidential information, which could adversely affect us. Competitors may infringe our patents, or challenge their validity or enforceability. To counter infringement or unauthorized use, we may be required to initiate legal proceedings, which are costly and time-consuming. An adverse outcome could result in our patents being invalidated, narrowed, or not issued, thereby affecting the protection of our drug candidates. Conversely, third parties may allege that our drug candidates infringe their patents or other intellectual property rights. We may be required to obtain licenses, redesign our candidates, or cease related activities until the dispute is resolved, any of which could materially delay or prevent the commercialization of our drug candidates. In addition, publicity around intellectual property disputes could negatively impact the perceived value of our drug candidates and our business.

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reputation, and could reduce the [REDACTED] of our shares. Overall, defending and resolving such disputes could impose substantial unanticipated costs and materially adversely affect our business, financial condition, results of operations and prospects.

We may face intellectual property disputes with our business partners or other third parties.

We may be subject to claims from former employees, collaborators, contractors, or other third parties asserting inventorship, ownership, or other rights in relation to our patents or other intellectual property. In enforcing our rights, we may face counterclaims challenging the validity, ownership, or enforceability of our intellectual property covering the development, manufacturing, or commercialization of our drug candidates. If unsuccessful in these proceedings, we could lose rights over key patents, or have such rights narrowed, invalidated, or rendered unenforceable. Such outcomes could materially affect our ability to develop and commercialize our drug candidates.

If our trademarks and trade names are not adequately protected, we may not be able to build brand recognition in our key markets, which may adversely affect our business.

We own certain registered trademarks, but may not always be able to secure or enforce protection across all jurisdictions relevant to our business. Our trademarks and trade names may be subject to opposition, cancellation, or claims of infringement, and could be challenged or declared generic. Failure to adequately protect our trademarks and trade names could impair our ability to build market recognition and brand value for our drug candidates, particularly in competitive therapeutic areas. Over the long term, if we are unable to establish and maintain such recognition, our competitiveness and business prospects may be materially and adversely affected.

Intellectual property rights may not adequately protect our drug candidates or ensure our competitive advantage.

The degree of protection that patents and other intellectual property rights afford is inherently uncertain and may not adequately prevent competitors from developing similar or alternative technologies, or from challenging the validity of our rights. For example, our pending patent applications relating to our drug candidates may not result in issued patents, or may be narrowed, invalidated, or held unenforceable following legal challenges; issued patents may not provide sufficient commercial protection if competitors are able to develop competing products that do not infringe our patents or are launched in jurisdictions where we lack protection; the commercial value of our patents may be limited by the time gap between patent issuance and the potential approval of our drug candidates, particularly given the finite patent term; competitors may conduct research and development in markets where we do not have adequate patent coverage, and use the resulting knowledge to develop competing products for launch in our key markets; and we may fail to obtain, maintain or expand adequate patent protection in all jurisdictions relevant to the development and commercialization of our drug candidates. Additionally, patents owned by others could adversely affect our ability to develop or commercialize our drug candidates, or allow competitors to develop biosimilar products once our patents expire.

Patent protection is limited, and third parties may circumvent our patents or develop competing products once our patents expire, which could materially and adversely affect our ability to commercialize our drug candidates.

The protection afforded by patents is inherently limited. In China, patents are generally valid for 20 years for invention patents and shorter periods for design and utility model patents, subject to the timely payment of maintenance fees. Competitors may seek to challenge the validity, scope or enforceability of our patents, or develop generic or biosimilar products that compete directly once our patents expire.

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Because the development and regulatory approval process for our drug candidates is lengthy, the patent term protecting certain drug candidates may expire before or shortly after commercialization. Patent term extensions, if available, are subject to regulatory discretion and may not provide sufficient protection to prevent competitors from entering the market. As a result, our ability to exclusively market our drug candidates could be materially and adversely affected, which may significantly limit any potential sales and profitability of our products.

If we are unable to protect the confidentiality of our trade secrets or secure ownership of intellectual property developed by our employees, consultants and contractors, our business and competitive position could be materially harmed.

In addition to our patents, we rely on trade secrets and other proprietary information, including know-how and technological expertise, to protect our drug candidates and maintain our competitive position. We seek to protect such information through confidentiality agreements with our employees, consultants, CROs and other third parties. However, these measures may not always be effective. Any breach of confidentiality obligations could result in the unauthorized disclosure or use of our trade secrets, and we may not have adequate remedies to prevent such disclosure. If our trade secrets are independently developed or lawfully obtained by a competitor, we may have no effective means to stop them from competing with us.

Moreover, many of our employees and consultants have previously worked for other pharmaceutical or biotechnology companies, including our competitors. We may face claims that our personnel have misappropriated such trade secrets or intellectual property. Defending against these claims could be costly, time-consuming, and distracting, and even if we ultimately prevail, we may suffer reputational harm or lose key personnel.

Further, we generally require our employees, consultants and contractors to assign to us any intellectual property developed in the course of their engagement. These agreements may not always be self-executing or enforceable. If we fail to secure ownership of intellectual property that we regard as our own, or if such agreements are breached, we may lose valuable rights in our drug candidates.

Changes in patent law could reduce the value of our intellectual property rights and impair our ability to protect our drug candidates.

Patent laws and judicial interpretations in China, the U.S., Europe and other jurisdictions are evolving and may narrow the scope, validity or enforceability of our existing and future patents. Such changes could reduce the commercial value of our patents, increase uncertainty in protecting our drug candidates, and adversely affect our business and prospects.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

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

As we continue to advance our pipeline candidates, including our core products, through various stages of clinical development and prepare for potential commercialization, we expect to significantly expand our operations and organizational structure. This will require us to enhance our R&D, clinical, regulatory, manufacturing, supply chain, and sales and marketing capabilities, or to engage qualified third parties to provide such capabilities on our behalf. We may also need to establish or expand relationships with additional strategic partners, suppliers, and other third parties to support the continued growth of our business.

Such expansion will place substantial demands on our management, operational and financial resources, and require the development of effective systems and controls. Our future success will depend, in part, on our ability to manage these growth initiatives effectively, attract and retain

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qualified personnel, and ensure our operations comply with applicable regulatory requirements. We cannot assure you that we will be able to effectively manage our growth, or that we will successfully develop and commercialize our drug candidates or build the necessary manufacturing, sales and marketing infrastructure to support commercialization.

We may be subject to product liability lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical testing and potential future commercialization of our drug candidates. We may be subject to claims if any of our drug candidates cause or are perceived to cause injury, adverse effects, or are otherwise found to be unsuitable during clinical trials, manufacturing, or commercialization. Any such product liability claims may include allegations of defects in manufacturing or design, improper or insufficient labeling, or inadequate disclosure of side effects or risks inherent in our products.

If we are unable to successfully defend against such product liability claims, we may be required to pay substantial damages or to limit, delay, or suspend our clinical trials or potential commercialization activities. The litigation process could require significant financial and management resources. In addition, any product liability claims, could result in: decreased demand for our drug candidates or any resulting products; suspension or delay of our ongoing or planned clinical trials; decreased willingness of patients or investigators to participate in future trials; adverse publicity or reputational harm; substantial monetary awards or settlement costs; diversion of management and scientific resources; and a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to defend ourselves against such claims, we may also be subject to potential civil or regulatory liabilities under PRC law, including the revocation of relevant permits or licenses, product recall, or suspension of related clinical activities. Besides, the time, costs, and resources required to do so could materially and adversely affect our business operations and delay the development of our pipeline 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 claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of our business. These may include matters relating to, among others, product liability, intellectual property rights, collaboration or service agreements, clinical research and development activities, employment or labor disputes, or other contractual matters. Any such claims, disputes or legal proceedings initiated by us or brought against us, whether with or without merit, may require significant management time and financial resources to resolve, and may materially and adversely affect our reputation, business operations and financial condition. Certain claims, disputes or proceedings may arise from our relationships with third parties such as our suppliers, CROs, clinical trial sites, licensors, and other service providers. Even if we are entitled to seek indemnification from these counterparties, we cannot assure you that they will be able to indemnify us in full, or in a timely manner, for any costs or losses that we may incur as a result of such claims, disputes, or proceedings.

Our Controlling Shareholders have had and will continue to have substantial influence over the outcome of shareholder actions in our Company. The interests of our Controlling Shareholders may not be aligned with the interests of our other shareholders.

Upon completion of the [REDACTED], our Controlling Shareholders will hold approximately [REDACTED]% of our total issued and outstanding Shares. As a result, our Controlling Shareholders will have substantial influence over our business, including decisions relating to mergers, consolidations, liquidation, the sale of all or substantially all of our assets, election of directors and other significant corporate matters.

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They may take actions that are not aligned with the interests of our other shareholders. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other shareholders of the opportunity to receive a premium for their shares as part of a sale of our Company, and may reduce the [REDACTED] of our Shares. Such concentrated control could also limit the ability of our minority shareholders to influence corporate decisions and may discourage any potential merger, takeover or other change of control transaction that our other shareholders might otherwise consider beneficial.

Our future success depends on our ability to retain key executives and to attract, hire, retain and motivate other qualified and highly skilled personnel.

Our success depends significantly on our continued ability to attract, retain and motivate qualified management and scientific personnel. Competition for experienced personnel in the biopharmaceutical industry is intense, and the pool of qualified candidates is limited. In recent years, the average staff cost in the biopharmaceutical sector, particularly for highly skilled R&D professionals, has continued to increase. We cannot assure you that we will be able to retain our key management or scientific staff, or that we will be able to attract qualified replacements in a timely manner should any of them depart. The loss of one or more members of our senior management or key scientific personnel could materially and adversely affect our research progress, product development, and overall business operations. As we continue to advance our clinical programs and prepare for potential commercialization, we expect to further expand our team and hire additional employees to support our development and operational needs. If we fail to effectively recruit, train, and retain these personnel, our business, financial condition, results of operations and prospects may be materially and adversely affected.

We may be subject to natural disasters, health epidemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Natural disasters, epidemics, acts of war, terrorism or other force majeure events beyond our control may adversely affect the economy, infrastructure and general business environment in the regions where we operate. Our operations, and those of our third-party research collaborators, suppliers, CROs, CDMOs and other service providers, may be affected by events such as floods, earthquakes, sandstorms, snowstorms, fires, droughts, outbreaks of communicable diseases such as COVID-19, SARS, avian influenza or other epidemic or pandemic diseases, power shortages, network failures or potential geopolitical conflicts. The occurrence or resurgence of any public health event, including COVID-19 or other infectious diseases, could materially disrupt our clinical trials, delay our R&D activities, and adversely affect the operations of our business partners and service providers. There can be no assurance that similar epidemics or other large-scale public health emergencies will not occur again in the future or that such events will not have a material adverse effect on our operations and clinical development progress.

Serious natural disasters or other force majeure events may result in damage to property, loss of data or biological samples, or temporary closure of our offices or laboratories, leading to significant interruption of our business operations. Since we rely on third parties for certain research, development and clinical operations, any disruption or delay in their services caused by such events may affect our ability to progress our pipeline candidates according to schedule. Our insurance coverage may not fully compensate for all losses under such circumstances.

Any of the foregoing events, or other events beyond our control, may materially and adversely affect the overall business sentiment, lead to instability in the markets in which we operate, delay our R&D activities, or otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

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Counterfeits of pharmaceutical products similar to our drug candidates and the illegal and/or parallel import of competing drugs in the global market could negatively affect our future sales and reputation.

Certain pharmaceutical products sold in the market may be manufactured without licenses or approvals. Some may be mislabeled or contain incorrect information about their ingredients or origin. These are known as counterfeit pharmaceutical products. Globally, enforcement against counterfeit drugs remains limited. Counterfeit drugs that resemble our future approved drug candidates may appear after commercialization. They are often of inferior quality and sold at lower prices. Such counterfeit drugs could reduce our sales and harm our reputation. Some counterfeit drugs may not contain the same active ingredients as our genuine drug candidates. They may be less effective, ineffective or even unsafe. Such incidents could lead to negative publicity, regulatory investigations or litigation. Counterfeit drugs in the global market may also undermine public confidence in innovative pharmaceutical products. If counterfeit or unqualified drugs enter the market and are mistaken for our approved drug candidates, our reputation could be damaged.

If we or our business partners fail to protect the data and privacy of subjects in our clinical trials, or the medical institutions that we cooperate with fail to do so, our reputation may be damaged and we may be subject to penalties or other regulatory actions.

We and our business partners collect and store clinical trial data, including non-personally identifiable information of clinical trial participants. This requires us, our CROs and medical institutions to maintain strict internal control systems to safeguard such information. The global regulatory environment governing data collection, use and transfer is complex and evolving. Data protection laws and regulations differ among jurisdictions and are subject to frequent amendments.

In the course of our business operations, data loss or unauthorized disclosure may still occur. Such incidents may result from human error, employee misconduct or system failure. We also rely on third parties, including principal investigators, hospitals and CROs, to handle and store patient data. Any leakage, misuse or unauthorized access to such data by our third parties may be perceived by patients as our fault. Unauthorized disclosure of participant information could cause public concern and harm our reputation. Complying with privacy and data protection laws may also impose substantial operational burdens. If the applicable rules change or are interpreted differently, we may be required to adjust our practices within a short time.

We are subject to stringent PRC laws and regulations relating to data privacy and cybersecurity, and we may be subject to cybersecurity review or other regulatory actions.

On December 28, 2021, the Cyberspace Administration of China (“CAC”), together with 12 other governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which became effective on February 15, 2022. For more details the MCR, see “Regulatory Overview” in this document.

As of the Latest Practicable Date, (i) we had not been informed or identified by the relevant governmental authorities as a critical information infrastructure operator; (ii) we had been primarily engaged in the discovery and development of TCE drug candidates for the treatment of solid tumors and had not conducted any business involving the collection, storage or processing of personal information of more than one million users through network technologies or internet-based platforms; and (iii) we had not been subject to any cybersecurity review, inquiry, notice, warning, or sanctions by the CAC or other competent authorities.

On September 24, 2024, the State Council issued the Regulation on the Administration of Cyber Data Security (《網絡數據安全管理條例》) (the “Cyber Data Security Regulation”), which will take effect on January 1, 2025. This regulation imposes new compliance requirements on network data processing, including the security and protection of network data, management of cross-border data transfer, and obligations of network service providers. A network data processor

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whose activities “affect or may affect national security” will be subject to cybersecurity review under Article 13 of the Cyber Data Security Regulation. The regulation does not clearly define the scope of “affect or may affect national security,” and its interpretation remains uncertain. If we were deemed to have engaged in network data processing activities that fall within such scope, we could be required to undergo cybersecurity review and may be subject to penalties, suspension of operations, or revocation of permits, which may materially and adversely affect our business operations.

We may be restricted from transmitting our scientific data or human genetic resources outside of China.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which set out the regulatory framework for the management and use of scientific data in China. Under these measures, enterprises in China are required to obtain government approval before transferring scientific data involving any state secret abroad or to foreign entities. Research funded at least in part by the Chinese government must also be filed with the relevant authority before the data can be published in any overseas academic journal. It remains uncertain whether our research and development of drug candidates would fall within the scope of the Scientific Data Measures. If the Scientific Data Measures or any subsequent regulations apply to us, we may need to obtain approvals before transmitting scientific data abroad, including preclinical or clinical trial data generated in China. We cannot assure you that we will be able to obtain such approvals in a timely manner, or at all. Any delay or failure to secure the necessary approvals could hinder our research and development process and materially and adversely affect our business, financial condition, results of operations and prospects.

In addition, the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》) promulgated in May 2019 and the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) promulgated in October 2020 impose additional approval requirements for the collection, storage, utilization and export of human genetic resources in China. If any of our research or clinical trials involve human genetic resources, we must obtain prior approval from the Ministry of Science and Technology of the PRC before transferring related data or materials outside of China. If our future research activities fall within the scope of these regulations, we may be required to apply for additional approvals. There is no assurance that such approvals can be obtained in a timely manner, or at all, which may materially and adversely affect our clinical development and collaboration with overseas partners.

Our future investments or acquisitions may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may in the future evaluate and pursue investments, in-licensing arrangements, joint ventures and acquisitions to augment our R&D, manufacturing or commercialization capabilities in China and overseas. We may engage in discussions or negotiations for one or more such transactions from time to time. These transactions involve significant challenges and risks, including: difficulties integrating into our operations the personnel, systems, quality and compliance programs, products and services of an acquired or invested company; challenges aligning technology platforms, internal controls and financial reporting of companies we acquire or invest in; disruption to our ongoing clinical development and pre-commercial activities, diversion of management attention and increases in operating expenses; loss of skilled professionals and of established relationships with collaborators, hospitals, CROs or other partners of the businesses we acquire or invest in; for minority or non-controlling investments, limited ability to influence the controlling partner or shareholder, which may prevent achievement of our strategic goals for the investment; new regulatory requirements and compliance risks that arise from operating in new jurisdictions or industries; actual or alleged historical misconduct or non-compliance by a target (or its affiliates) prior to our transaction that could trigger negative publicity, investigations or liability for the target or for us; unforeseen or hidden liabilities or costs that adversely affect us after

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completion; regulatory reviews and approvals, including anti-monopoly/competition filings and other transactional clearances, that could delay, condition or prohibit a proposed transaction; the risk that any pending or future proposed transaction does not close; the costs of identifying and consummating transactions; use of substantial cash, incurrence of debt or potentially dilutive issuances of equity securities to finance transactions; significant goodwill impairment charges and amortization of acquired intangible assets; and failure to realize expected synergies, cost savings or growth opportunities within the anticipated timeframe, or at all.

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

We may evaluate potential acquisitions and strategic partnerships, including in-licensing or acquiring complementary technologies, intellectual property rights or manufacturing capabilities. Any completed, in-process or potential acquisition or strategic partnership may entail risks, including: increased operating expenses and cash requirements; the assumption of additional indebtedness or contingent or unforeseen liabilities; assimilation of operations, technology, internal controls and intellectual property of an acquired or partnered company, including difficulties associated with integrating new personnel and systems; diversion of management's attention from our existing R&D and clinical programs to pursuing or integrating such strategic transactions; retention of key employees, loss of key personnel or uncertainties in maintaining key collaborations and business relationships; risks and uncertainties associated with the counterparties to such transactions, including their R&D progress, product pipeline and regulatory approvals; and/or our inability to generate revenue or achieve anticipated synergies from acquired technology and/or partnered products sufficient to meet our objectives or offset the associated acquisition or collaboration costs.

As a result, we may not be able to realize the intended benefits of, or may choose not to proceed with, any potential collaboration, strategic partnership or in-licensing opportunity if we are unable to successfully integrate such new assets or operations into our existing business. Any such failure or delay could slow our clinical progress, increase our costs or otherwise adversely affect our operations and prospects. We also cannot be certain that any future collaboration, partnership or acquisition will ultimately justify the investment or deliver the expected outcomes. If we are unable to reach agreements with suitable partners on acceptable terms or at all, we may need to independently continue certain R&D or commercialization activities, which may require additional time, expertise and capital. In addition, if we undertake acquisitions, we may assume or incur debt obligations, incur one-time transaction expenses or recognize intangible assets that could result in significant future amortization charges.

If our CROs, CDMOs or other contractors and business partners fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business and operations.

We are subject to numerous environmental, health and safety laws and regulations in the jurisdictions in which we operate, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our R&D activities may involve the use of small quantities of hazardous or flammable materials and may generate limited hazardous waste. In addition, we rely on third parties, including CROs, CDMOs and other business partners, to conduct certain research, manufacturing and testing activities on our behalf. These parties may also be subject to environmental, health and safety laws and regulations in their respective jurisdictions. We cannot eliminate the risk of contamination, injury or environmental incidents arising from the use, handling or disposal of hazardous materials by our CROs, CDMOs or other partners. In the event of an accident, we could be held jointly liable for any

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resulting damages, and such liabilities could exceed our available resources. We may also incur significant costs or penalties to remedy or mitigate such events or to comply with any orders or corrective actions imposed by relevant authorities.

In addition, we may incur substantial costs to ensure compliance with current or future EHS laws and regulations. These laws and regulations may become more stringent over time and may require us or our third-party partners to upgrade facilities, adopt new safety measures or modify operating procedures.

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

We conduct our R&D primarily in China, and may in the future seek regulatory approvals and commercialize our drug candidates in China, the U.S. and other jurisdictions. Our current and future operations may be subject to healthcare, anti-kickback, fraud and abuse, anti-bribery laws and physician payment transparency laws and regulations, including the Anti-Kickback Statute, the False Claims Act, and the Federal Physician Payment Act, as well as similar laws and regulations in China and other countries. These laws generally prohibit the offer or payment of any remuneration to induce the referral of patients or the purchase, lease, or order of any healthcare items or services reimbursable by government programs, and require transparency in payments or transfers of value made to healthcare professionals and institutions. Also, our potential expansion or business cooperation outside China may subject us to laws such as the Foreign Corrupt Practices Act of the U.S., which prohibits making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. There are uncertainties as to how these laws and regulations may apply to our current or future operations, particularly as we continue to collaborate with hospitals, physicians, CROs, CDMOs and other business partners in different jurisdictions. Efforts to ensure compliance with such laws may involve significant time, cost and resources.

Our business significantly depends on our reputation, and any negative publicity on us or our failure to maintain and enhance our recognition and reputation may materially and adversely affect our business, financial condition, results of operations and prospects.

We believe that the awareness and reputation of our brand and our research capabilities are essential to our success. Our reputation is closely linked to the perceived quality and integrity of our scientific research, the progress and outcomes of our clinical trials, and the professional conduct of our management and employees. Negative publicity concerning any of these aspects could harm our reputation and adversely affect our ability to attract collaboration opportunities, key personnel, investors and business partners.

As we continue to advance our drug candidates and expand our operations, we may increasingly rely on third parties, such as CROs, academic collaborators, consultants and other external partners. Because we have limited control over these third parties, any actual or perceived misconduct, data inaccuracy, regulatory non-compliance or unethical behavior by them could negatively affect our reputation.

Our reputation may also be affected by adverse developments in the biotechnology and pharmaceutical industries in general, including negative media coverage or regulatory inquiries concerning other market participants. If negative publicity or market speculation arises in connection with our drug candidates, clinical trial results or regulatory interactions, our reputation and credibility may be materially damaged. Any such event could reduce confidence among patients, healthcare professionals, investors and regulators, delay our development plans.

RISK FACTORS

Our information technology systems, or those of our CROs, CDMOs or other contractors and business partners, may fail or suffer security breaches.

Our information technology systems and those of our CROs, CDMOs and other external service providers are vulnerable to security threats and system failures. These threats may include computer viruses, unauthorized access, cyberattacks, hacking, data corruption, power failures, telecommunication interruptions or other unexpected events. Any such incident could lead to a loss of or damage to our critical data or systems and could cause material disruption to our research and development activities.

Our operations rely heavily on the storage and transmission of a large volume of confidential scientific data, clinical trial data and other proprietary information. If our systems or those of our contractors were to be compromised, our clinical data might be lost, corrupted or disclosed without authorization. If any clinical data relating to our drug candidates were lost or destroyed, this could result in delays in regulatory filings or approvals, require us to repeat pre-clinical or clinical studies, and significantly increase our costs.

In addition, any extended downtime, loss of access to key systems or failure to properly back up data could adversely affect our ability to recover or reproduce important research information. To the extent that any disruption or security breach results in data loss, unauthorized disclosure of proprietary or personal information, or other operational interruptions, we could be subject to liability and the development progress of our drug candidates could be delayed.

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

We maintain insurance coverage in accordance with applicable PRC laws and regulations and industry practices. Our insurance primarily covers auto insurance, and liability insurance for clinical trials. However, we do not currently maintain insurance coverage for certain specific risks such as environmental liability or potential product-related losses. Given the nature of our business, our operations may be exposed to various risks not fully covered by existing insurance policies. If any event occurs that gives rise to a claim not fully covered by our insurance, we may have to bear the associated losses, which could result in significant financial costs and diversion of management attention. Our insurance may be insufficient to cover all potential liabilities that may arise in connection with our operations.

Difficult conditions and turbulence in the global economic, political and financial environment may adversely affect our business, financial condition, results of operations and prospects.

Uncertain global economic, political and financial conditions, including fluctuations in interest rates, exchange rates, inflation, liquidity of capital markets and investor sentiment, may materially affect our operations and financing capabilities. Global market volatility, driven by recent geopolitical tensions, changes in monetary policies of major economies, and heightened inflationary pressure, has increased the uncertainty of capital availability and funding costs for companies operating in emerging markets such as China. As a pre-commercial biotechnology company that relies heavily on external funding for our R&D activities, our business and prospects are particularly sensitive to the global financing environment. A tightening of global liquidity or a sustained high interest rate environment may limit investors' willingness to finance early-stage biotechnology companies, making it more difficult or costly for us to raise additional capital through equity or debt financing. Any downturn or volatility in the capital markets could therefore delay our financing plans, disrupt our R&D programs, and adversely affect our financial position. Moreover, prolonged market instability, investor risk aversion or a global economic recession could also negatively impact our collaboration partners, suppliers, CROs and other counterparties, which may lead to delays in our ongoing projects and increase our operational costs.

RISK FACTORS

RISK RELATING TO DOING BUSINESS IN THE JURISDICTIONS WHERE WE OPERATE

Changes in economic, social conditions, policies and geopolitical relationships may materially affect our business, financial condition, results of operations and prospects.

Substantially all of our operations and assets are located in China, and our business performance depends significantly on the overall economic, social and policy environment in China. The PRC government has implemented and may continue to implement various policies and regulatory measures to adjust and guide the domestic economy, healthcare system and pharmaceutical industry. While such measures may benefit the general market environment, they may also adversely affect our operations, funding environment or growth prospects.

In addition, the ongoing uncertainties in global macroeconomic conditions and geopolitical relations may indirectly impact the PRC pharmaceutical industry, particularly with respect to the import of research materials, technology exchange and capital market sentiment. Further deterioration in geopolitical relations may affect the overall investment sentiment, capital flow, and supply of research materials or equipment in China pharmaceutical industry, which could indirectly impact our business operations and prospects. Any adverse developments in these aspects could negatively affect our business operations, financial condition and prospects.

International trade policies and relations may have a material adverse effect on our business and operating results.

Recent U.S. legislative and policy developments, including the BIOSECURE Act enacted as part of the U.S. National Defense Authorization Act for Fiscal Year 2026, reflect increased regulatory focus on biotechnology-related procurement, funding and supply chains. Although the BIOSECURE Act is primarily directed at U.S. federal procurement and federally funded programs, it restricts U.S. government engagement with entities designated as “biotechnology companies of concern” (“BCCs”) and may have indirect or downstream effects on commercial relationships and compliance expectations. In addition, evolving U.S.-China trade policies, including tariffs, export controls or other regulatory measures, may increase operational costs, limit access to certain markets, affect the availability or pricing of materials and services, or adversely impact our future business expansion strategies.

We are of the view that the BIOSECURE Act, together with other U.S. trade restrictions and tariffs, would not have a material adverse impact on our business, primarily because we currently conduct our clinical trials in China and do not have ongoing clinical trials in the U.S., and we are not a recipient of any U.S. federal government contracts, loans, grants, or funding, and we do not anticipate applying for such contracts, loans, grants, or funding in the foreseeable future. Even if we initiate clinical trials in the U.S. in the future, the U.S. tariffs would not have a material impact. Per the Harmonized Tariff Schedule Code 9817.85, product candidates to be used exclusively for development, testing, product evaluation, or quality control purposes are exempt from tariffs. Also, none of our major suppliers qualifies as or has been designated as a BCC under the BIOSECURE Act. Even if any of our suppliers or business partners were to be designated as a BCC or become subject to restrictions in the future, we believe we would be able to transition to alternative qualified suppliers to meet our operational needs. We have taken measures to broaden our supplier base and ensure the availability of alternatives in the event of a disruption with one or more suppliers. However, future amendments to the BIOSECURE Act or evolving regulatory interpretations may expand the scope of designated BCCs or broaden their application. We cannot assure you that we or our business partners, or their collaborators, will not be designated or otherwise become subject to additional restrictions. If any such events were to occur, our business operations, results of operations, financial condition, and future prospects could be materially and adversely affected.

RISK FACTORS

There may be new laws or regulations promulgated or interpretations of the laws and regulations in the future that may affect our business, financial condition, results of operations and prospects.

We are subject to extensive laws, rules and regulations in China where we operate. Given the continuous development of the PRC regulatory environment and the dynamic nature of the healthcare and pharmaceutical industries, new laws or regulations may be promulgated, or existing ones may be amended or reinterpreted from time to time. We are required to stay abreast of, and comply with, these evolving legal and regulatory requirements in a timely manner.

In particular, the regulatory regime governing the pharmaceutical industry in China has undergone significant changes in recent years and continues to evolve. Relevant authorities, including the NMPA, may from time to time introduce new rules or amend existing policies governing drug research, clinical trials, registration, production and commercialization. Such regulatory changes or their implementation may lead to increased compliance costs, additional approval requirements, or extended review timelines, any of which could delay our R&D progress, increase our operating costs, or adversely affect our business, financial condition and results of operations.

Procedures on the remittance of Renminbi into and out of the PRC may affect our ability to pay dividends and other obligations.

We are a company incorporated under the laws of the PRC, and our business operations are primarily conducted within the PRC. Substantially all of our future revenues are expected to be denominated in Renminbi. We may need to convert Renminbi into foreign currencies to pay dividends, if any, to our shareholders after our [REDACTED], or to satisfy other foreign currency-denominated obligations.

Under the current PRC foreign exchange regulations, current account transactions, such as dividend payments, generally do not require prior approval from the State Administration of Foreign Exchange (“SAFE”), but we are required to present supporting documentation and conduct such transactions through designated foreign exchange banks within the PRC. Capital account transactions, such as repayment of foreign loans or remittance of [REDACTED] from overseas [REDACTED], are subject to prior approval or registration with the relevant authorities. Any change, delay or restriction in the applicable foreign exchange policies could limit our ability to transfer funds out of the PRC, which may in turn adversely affect our financial position and ability to pay dividends or meet other funding needs.

Holders of our H Shares may be subject to PRC tax obligations.

Under applicable PRC tax laws, both the dividends we pay to non-PRC resident individual holders of H shares (“**Non-Resident Individual Holders**”), and gains realized through the sale or transfer by other means of H shares by such shareholders, are subject to PRC individual income tax at a rate of 20%, unless reduced by applicable tax treaties or arrangements. And the dividends we pay to, and gains realized through the sale or transfer by other means of H shares by non-PRC resident enterprise holders of H shares are both subject to PRC enterprise income tax at a rate of 10%, unless reduced by applicable tax treaties or arrangements. With respect to Non-Resident Individual Holders, income received from transfer of stocks of listed companies are currently exempt from individual income tax pursuant to applicable PRC regulations. However, the aforesaid regulations have not expressly provided that individual income tax shall be exempted from non-PRC resident individuals on the sale of shares of PRC resident enterprises listed on overseas stock exchanges. On February 3, 2013, the State Council approved and promulgated the Notice of Suggestions to Deepen the Reform of System of Income Distribution (《國務院批轉發展改革委等部門關於深化收入分配制度改革若干意見的通知》). On February 8, 2013, the General Office of the State Council promulgated the Circular Concerning Allocation of Key Works to Deepen the Reform of System of Income Distribution (《國務院辦公廳關於深化收入分配制度改革重點工作分工的通知》). According to these two documents, the PRC government may be introducing

RISK FACTORS

regulations or policies that have the effect of cancelling foreign individuals’ tax exemption for dividends obtained from foreign-invested enterprises. There is no assurance that any gains on the sales of our H Shares and the dividend thereon will not be subject to PRC income taxes in the future.

There may be uncertainties in effecting service of legal process and enforcing foreign judgments against us and our management in China.

We are a company incorporated under the laws of the PRC, and substantially all of our assets and senior management are located in China. Similar to the difficulties faced by most of the countries around the world on effecting service of process and enforcing judgments obtained from foreign countries, it may be difficult for [REDACTED] outside the PRC to effect service of process upon us or our Directors or senior management within or outside the PRC, or to enforce judgments obtained in jurisdictions outside the PRC against us or them.

Although the Supreme People’s Court of the PRC and the government of the Hong Kong Special Administrative Region have entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), it does not apply to certain judgments of civil and commercial matters. Consequently, [REDACTED] may face difficulties in seeking to enforce judgments against us or our management in China.

We are subject to risks in relation to our social insurance and housing provident fund contributions.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and housing provident funds for our employees in accordance with relevant PRC laws and regulations.

During the Track Record Period and as of the Latest Practicable Date, we did not make full contributions to the social insurance and housing funds for employees in accordance with the relevant PRC laws and regulations and such shortfall amount was not material. We had not been subject to any administrative actions, fines or penalties during the Track Record Period and up to the Latest Practicable Date due to such non-compliance and we had not received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing provident funds as of the Latest Practicable Date. We cannot assure that we will not be required to pay any deemed shortfalls or be subject to penalties or fines regarding social security insurance and housing provident funds contributions, any of which may have an adverse effect on our business and results of operations.

Pursuant to the Article 19 of the Supreme People’s Court’s Interpretation (II) on Several Issues Concerning the Application of Law in Labour Dispute Cases (which took effect in September 2025) (最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)) (the “**New Judicial Interpretation**”), if an employer and an employee agree or the employee undertakes that social insurance contributions are not required to be paid, the People’s Court shall deem such agreement or undertaking invalid, and where an employer fails to pay social insurance contributions in accordance with the law, and the employee requests to terminate the labor contract and claims economic compensation from the employer in accordance with the PRC Labor Contract Law, the People’s Court shall support such claims. Our Directors are of the view that the New Judicial Interpretation would not have a material adverse effect on our business, financial condition or results of operations, based on the following considerations: (i) as advised by our PRC Legal Advisor, the New Judicial Interpretation does not affect the compliance status of our social insurance contributions, (ii) it does not influence the assessment of any contribution shortfalls or increase our exposure to penalties.

RISK FACTORS

RISK RELATING TO THE [REDACTED]

There has been no prior [REDACTED] for our H Shares and the liquidity and [REDACTED] of our H Shares may be volatile.

Prior to the completion of the [REDACTED], there has been no public market for our H Shares. There can be no assurance that an active [REDACTED] for our H Shares will develop or be sustained after the completion of the [REDACTED]. The [REDACTED] will be determined by negotiations between our Company and the Sole Sponsor (for itself and on behalf of the [REDACTED]), and may not be indicative of the price at which our H Shares will be [REDACTED] following the completion of the [REDACTED]. The [REDACTED] of our H Shares may fluctuate significantly and may fall below the [REDACTED] at any time after the completion of the [REDACTED].

The [REDACTED] of our H Shares may be volatile, which could result in substantial losses to you.

The [REDACTED] of our H Shares may be volatile and could fluctuate widely in response to factors beyond our control. In particular, the market performance of other companies in the biotechnology and pharmaceutical industry, especially those with business operations located mainly in Chinese Mainland and [REDACTED] in Hong Kong, may affect the volatility in the price of and [REDACTED] for our H Shares. A number of biotechnology and biopharmaceutical companies [REDACTED] in Hong Kong have experienced significant fluctuations in their [REDACTED] after [REDACTED], including substantial declines from their initial [REDACTED] prices. The [REDACTED] performance of such companies may affect [REDACTED] sentiment toward biotechnology companies [REDACTED] in Hong Kong and, consequently, may impact the [REDACTED] performance of our H Shares. Pursuant to applicable PRC laws and regulations, within one year following the [REDACTED], all existing Shareholders (including the Pre-[REDACTED] Investors) will be subject to lock-up requirements and will not be permitted to dispose of any of the Shares held by them. Due to such restrictions, the liquidity and [REDACTED] of our H Shares in the short term following the [REDACTED] may be limited. These factors could materially affect the [REDACTED] and volatility of our H Shares, regardless of our actual business performance.

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

The [REDACTED] of our H Shares could decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the public market, the issuance of new shares or other securities, or the perception that such sales or issuances may occur. As a pre-revenue biotechnology company, we expect to incur significant expenditures in connection with our ongoing R&D and clinical trial activities, and we may from time to time seek to raise additional capital through [REDACTED] or private [REDACTED]. Any future sales, or perceived sales, of a substantial amount of our securities, including in connection with potential follow-on [REDACTED], could materially and adversely affect the [REDACTED] of our H Shares and our ability to raise capital on favorable terms. In addition, our Shareholders may experience dilution in their shareholdings if we issue additional shares in the future.

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

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, [REDACTED] purchasing the [REDACTED] in the [REDACTED] will experience an immediate dilution in the [REDACTED] consolidated net tangible asset value per Share. As we are still in the R&D stage and have not yet generated any revenue from product sales, we may in the future conduct additional equity financings to fund our pipeline development, commercialization capabilities, and potential strategic collaborations. As a result, purchasers of the [REDACTED] may experience further dilution in the net tangible asset value per Share if we issue additional Shares in the future at a price lower than the net tangible asset value per Share at that time.

RISK FACTORS

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

We are an early-stage biopharmaceutical company with no commercialized products and have incurred net losses since our inception. We expect to continue to incur losses for the foreseeable future as we advance the development and commercialization of our pipeline drug candidates. We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline drug candidates and to support our ongoing R&D and operational activities. As a result, we do not expect to declare or pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] in our H Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to declare and pay dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend upon various factors including our future results of operations, financial condition, cash flow, capital requirements, and the amount of distributions received from our subsidiaries. Dividends under PRC law and our Articles may only be paid out of distributable profits, which refer to after-tax profits as determined under PRC GAAP or IFRS, whichever is lower, after making the necessary allocations to statutory reserve funds. Accordingly, 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 assurance that our H Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased 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.

Certain statistics contained in this Document are derived from various official government sources and have not been independently verified by us.

Certain statistics, information and data contained in this Document relating to China and elsewhere in the world, and the industry in which we operate have been derived from various official government publications. We believe that the sources of the information are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. However, information and statistics from official government sources have not been independently verified by us or any other parties involved in the [REDACTED] and no representation is given as to their accuracy. Due to possibly flawed or ineffective collection methods and analysis or discrepancies between published information and market practice, such statistics, information and data in this Document may be inaccurate or may not be comparable to statistics, information and data produced with respect to other economies. Further, there is no assurance that they are stated or compiled on the same basis or with the same degree of accuracy as the case may be in other jurisdictions. In all cases, [REDACTED] should give consideration as to how much weight or importance they should attach to or place on such facts.

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

We strongly caution you not to rely on any information contained in press articles, online commentaries or other media coverage regarding us, our industry or the [REDACTED]. Prior to the publication of this Document, there may have been, and subsequent to its publication there may continue to be, press and media coverage relating to our Company, our business, our industry and the [REDACTED]. Such media coverage may include references to information, estimates or projections that do not appear in this Document, including financial or operational data, valuation analyses, or clinical and research updates regarding our pipeline drug candidates. None of our Company, the Sole Sponsor or any other person involved in the [REDACTED] has authorized or verified the accuracy or completeness of any such information or publication, nor do we accept any responsibility for such information. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information. To the extent that any such information is inconsistent with or conflicts with the information contained in this Document, we disclaim responsibility for it, and you should not rely on such information in making your [REDACTED] decision.