
RISK FACTORS

You should carefully consider all of the information set out in this document, including the risks and uncertainties described below, before making an [REDACTED] in our Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] price of our Shares could decline due to any of these risks, 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.

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR PRODUCT CANDIDATES

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

Our ability to generate revenue and become profitable is substantially dependent on our ability to successfully complete the development of our product candidates, obtain necessary regulatory approvals, and manufacture and commercialize our product candidates. We have invested and will continue to invest substantial efforts and resources in our product candidates. The success of our product candidates will depend on several factors, including but not limited to, (i) favorable safety and efficacy data from our clinical trials and other studies, (ii) successful enrollment of patients in, and completion of, trials, as well as completion of preclinical studies, (iii) sufficient resources to discover additional product candidates and successful identification of potential product candidates based on our research or business development methodology or search criteria and process, (iv) competition with other product candidates and marketed products, (v) the performance by CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data, (vi) receipt of regulatory approvals from the NMPA, the FDA or other comparable regulatory authorities for our clinical product candidates, or assignment of INCI names of our functional aesthetic product candidates, (vii) obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates, (viii) ensuring we do not infringe, misappropriate or otherwise violate intellectual property rights of third parties, and successfully defending against any relevant claims by third parties, (ix) establishing sufficient commercial manufacturing capabilities, (x) successfully launching commercial sales of our product candidates, if and when approved, (xi) obtaining and maintaining favorable governmental and/or private reimbursement from third-party payers for our product candidates, if and when approved, (xii) obtaining sufficient supplies of any products or marketed products that are used in combination with our product candidates, competitor products, or comparison products that may be necessary for use in clinical trials for evaluation of our product candidates, (xiii) continued acceptable safety profile of our product candidates following regulatory approval, if and when received, and (xiv) stable and supportive domestic policies, favorable international environment and good relationships among nations.

If we do not achieve one or more of the aforementioned factors in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for and/or successfully commercializing our product candidates.

We may not be able to identify, discover or develop new product candidates, or to identify additional opportunities for our product candidates, to expand or maintain our product pipeline.

The development and manufacturing of oncolytic immunotherapies and engineered exosomes involve significant technical challenges. In addition, identifying new product candidates, targets, or expanding into additional indications requires substantial technical, financial, and human resources. We cannot guarantee that we will be successful in identifying potential new product candidates. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for development for a number of reasons, including but not limited to the following factors, (i) the research methodology used may not be successful in identifying

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potential indications and/or new product candidates, (ii) there may be a lack of transferability of experimental results obtained in the laboratory testing in cells or from animals into clinical treatment and safety outcomes in human subjects, including unexpected toxicities in humans, (iii) potential product candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired safety and efficacy, (iv) it may take greater resources to identify additional opportunities for our product candidates or to develop suitable potential product candidates, thereby limiting our ability to diversify and expand our product portfolio, or (v) we may not be able to manufacture the right dosage form to match the appropriate route of administration during the development of our product candidates.

Accordingly, there can be no assurance that we will be able to identify new product candidates or additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially and adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts.

The global biologics markets are constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. In 2023, 2024 and 2025 and the five months ended May 31, 2026, our research and development expenses were RMB136.2 million, RMB111.5 million, RMB112.0 million and RMB31.0 million, respectively. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, and any failure to effectively adapt or accelerate the adoption of new technologies in our R&D of novel therapies could result in a significant waste of our human and financial resources.

We face intense competition and our competitors may discover, develop or commercialize competing products faster or more successfully than we do, which may adversely affect our ability to successfully commercialize our product candidates.

The development and commercialization of new products is highly competitive. Some of our competitors have greater financial, technical and human resources, more established commercialization infrastructure as well as more product candidates in late-stage clinical development than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may concentrate resources among fewer competitors. These competitors may have advantages in recruiting talent, securing clinical trial sites and patients, and acquiring technologies critical to our programs.

Even if our product candidates have been successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, we will still face competition in terms of safety, efficacy, tolerability, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price, patent position and other factors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or gain better acceptance for the same target markets as ours, which will undermine our competitive position. Disruptive technologies and medical breakthroughs may further intensify the competition and render our product candidates obsolete or noncompetitive.

Clinical development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis.

To obtain regulatory approval for the sale of our clinical drug candidates, we are required to conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in human. Clinical trials are expensive, difficult to design and implement, and the clinical outcomes are subject to high uncertainty. We may experience numerous unexpected events during, or as a result of, clinical trials, including but not limited to situations whereby, (i) we or our investigators may be required to

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commence a clinical trial or conduct a clinical trial at an unexpected trial site, (ii) the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, (iii) the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated, (iv) our CROs and CDMOs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, (v) the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate, (vi) the costs of clinical trials of our drug candidates may be substantially higher than anticipated, (vii) our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials, (viii) regulators may require that we or our investigators suspend or terminate clinical research for reasons such as non-compliance, and (ix) clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or be required, to conduct additional clinical trials or abandon drug development programs.

Under these circumstances, we may be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all, or obtain approval for proposed indications that are not as broad as intended. Such delays may result in increases in our drug development costs, and could also shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates.

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

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to timely enroll a sufficient number of patients who opt to participate and remain in the trial until its conclusion. We may fail to initiate or continue clinical trials, or could only delay these trials, for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in our clinical trials, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to, (i) the design of the trial, (ii) the patient eligibility criteria defined in the protocol, (iii) the severity of the disease under investigation, (iv) our ability to obtain and maintain patient consents, (v) the experience and competencies of our third-party contractors, (vi) our ability to select clinical trial sites and to recruit clinical trial investigators with the appropriate competencies and experience, (vii) clinicians’ and patients’ perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating, (viii) the outbreak of epidemics or pandemics, and (ix) the availability of approved therapies that are similar in mechanism to our product candidates.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients may opt to enroll in a trial conducted by one of our competitors instead of ours. As the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent completion of these trials and materially and adversely affect our ability to advance the development of our product candidates.

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Adverse events caused by our product candidates could interrupt, delay or halt relevant trials, delay or prevent regulatory approval or registration process, limit the commercial profile of an approved product.

Undesirable adverse events caused by our product candidates, or caused by our product candidates when used in combination with other drugs, could cause significant negative consequences. These may include, among others, delays, interruptions, or termination of clinical trials, regulatory delays, restrictions, or loss of approvals, increased development and compliance costs, changes to product labeling or administration, slower patient enrollment or higher dropout rates; product recalls, litigation, or regulatory investigations, as well as potential harm to our reputation. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, and could significantly harm our business, results of operations and prospects.

Results of early clinical trials may not be predictive of future trial results.

The results of early clinical trials may not be predictive of the success of later phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily predict successful final results. When our product candidates enter in later stages of clinical trials, they may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials.

In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same product candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, changes to manufacturing processes or product formulation during development, differences in the number and geographic distribution of clinical trial sites, and evolving standards of care that may affect patient resistance or treatment response. Earlier trials and may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our product candidates. If so, we would have expended a significant amount of capital to progress the relevant product candidates to that stage, and would not realize any revenue on such product candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially and adversely affect our business, financial condition, results of operations and prospects.

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

Before obtaining regulatory approvals for the commercialization of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates for their proposed indications in humans. Undesirable adverse events caused by our product candidates could cause the interruption, delay, suspension or termination of our clinical trials and result in a more restrictive label or the delay or denial of regulatory approval. In such an event, our clinical trials could be suspended or terminated and we may be required to cease further development of, or deny approval of, our product candidates for any or all targeted indications. In addition, our clinical trials may not generate meaningful clinical response or have other unexpected characteristics, such as the short-term duration of response and insufficient enhancement of overall survival benefits.

If the results of clinical trials of our product candidates are not positive or only modestly positive for proposed indications, or if they raise safety concerns, regulatory approvals for our product candidates may be delayed or denied, and we may be required to conduct additional clinical trials or other testing of our product candidates beyond our current development plan. In addition, conditional regulatory approval 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. Having expended a significant amount of capital

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to progress our product candidates, failure to demonstrate safety and efficacy to the satisfaction of regulatory authorities or to obtain regulatory approval could prevent us from realizing any revenue on such product candidates and materially and adversely affecting our business, financial condition, results of operations and prospects.

In addition, if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such products, it could result in a number of potentially significant negative consequences. For example, we may be forced to suspend marketing of the product and conduct post-market studies, as well as develop risk evaluation and mitigation measures for the product. Also, approvals for the commercial sales of the product may be withdrawn, and additional warnings on the label may be required to be added. We could also be required to recall our products and be sued and held liable for harm caused to subjects or patients. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

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

As we have limited financial and managerial resources, we focus our pipeline on research platform and product candidates that we identify for specific indications. Our spending on current and future research and development platform and product candidates for specific indications may not yield any commercially viable products. Accordingly, our resource allocation decisions may cause us to fail to capitalize on other viable commercial products or profitable market opportunities. If we cannot accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Furthermore, we may from time to time pause or sequence certain clinical development activities for our drug candidates in order to prioritize resources for the advancement of selected indications. While such pauses have been strategic decisions not driven by safety or efficacy concerns, and we may reactivate such clinical programs at a later stage at our own discretion, there can be no assurance that our portfolio prioritization and sequencing decisions will prove optimal, that any paused or reactivated clinical programs will achieve their clinical or regulatory objectives, or that we will have sufficient resources to advance multiple clinical programs simultaneously. Any delays or failures in the development of lead indications as a result of these decisions could adversely affect our business, financial condition and prospects.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, process, and analyze data and information from our preclinical studies and clinical trials, and rely on such data to advance the development of our product candidates. Because data in the healthcare industry is fragmented, inconsistent, and incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, errors or omissions may occur, and mistakes in the capture, input, or analysis of these data could materially harm our business, prospects and reputation.

In addition, we rely on certain third parties to monitor and manage data for some of our ongoing studies and control only certain aspects of their activities. If any of these third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see “— Risks Relating to Our Reliance on Third Parties — We work with various third parties to develop our product candidates. If these third parties do not successfully carry

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out their contractual duties, fail to comply with regulatory requirements, or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, and our business could be materially harmed.”

Interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, whose results, related findings and conclusions are subject to changes following a more comprehensive review of such data. We also make assumptions, estimations, calculations and conclusions as part of our analyses progress, for which we may not necessarily receive or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported by us may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

We may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risks that one or more of the clinical outcomes may materially change along with subject enrollment where more subject data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors could result in volatile prices of our Shares after the [REDACTED].

Moreover, others may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidates.

We face potential product liability claims or lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of the trials and any future commercialization of our product candidates. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical and other testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. If we cannot successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates.

Moreover, liability claims may result in decreased demand for our product candidates, injury to our reputation, withdrawal of clinical trial subjects and inability to continue clinical trials, initiation of investigations, costs to defend the related litigation, a diversion of management’s time and our resources, substantial monetary awards to trial subjects or patients, product recalls, withdrawals, or labeling, marketing or promotional restrictions, loss of revenue, exhaustion of any available insurance and our capital resources, the inability to commercialize any approved product candidate, and a decline in the market price of our Shares.

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RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

The manufacturing of biopharmaceutical products is a complex process, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.

As of the Latest Practicable Date, we had not commercialized any product candidates under the clinical regulatory pathway. As a result, we have limited experience in manufacturing biopharmaceutical products on a commercial scale, which is a complex process, in part due to strict regulatory requirements. We cannot assure you that issues relating to the manufacturing of our product candidates will not occur in the future. We also face certain risks in relation to the CDMOs we engage for manufacturing activities. See “— Risks Relating to Our Reliance on Third Parties — We may rely on third parties to manufacture our products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our clinical development and commercialization needs. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels.”

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

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

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

The oncolytic immunotherapy market is still at a nascent stage. If the market does not continue to grow, grows slower than we expect or fails to grow as large as we expect, our business, results of operations, financial condition and prospects could be materially and adversely affected.

The global oncolytic immunotherapy market, including the U.S. and China, remains at a relatively early stage of development, characterized by historically slow growth and low penetration rates. As a result, it remains uncertain to what extent market acceptance and demand for oncolytic immunotherapies will continue to expand, if at all. According to Frost & Sullivan, the global oncolytic immunotherapy drug market reached only US\$107.2 million in 2025, representing a CAGR of merely 6.1% from 2019 to 2025. In 2025, the relevant market size in the United States amounted to US\$70.9 million, while the market in China was approximately US\$7.0 million. These figures reflect the modest scale of the current market and underscore the uncertainty surrounding future demand and adoption of oncolytic immunotherapies globally.

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Our product candidates, once approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. Potential patients and their physicians may be inclined to use conventional standard-of-care treatments rather than trying out a novel approach. Further, given the novelty of our product candidates, patients and medical personnel may need substantial education and training. In addition, physicians, patients and third-party payers may prefer other products to ours. If our product candidates do not achieve an adequate level of acceptance, the commercialization of such product candidates may become less successful or profitable than we had expected. Similarly, our aesthetics ingredient candidates may be less competitive than other ingredients that have been widely accepted in the aesthetics industry.

The degree of market acceptance of our product candidates, if approved for commercial sales, will depend on a number of factors, including, but not limited to, (i) the indications for which our product candidates target and the market demand for the treatment of those indications, (ii) efficacy and safety of our product candidates, (iii) the potential and perceived advantages of our product candidates over alternative treatments, (iv) acceptance by physicians, operators of hospitals and clinics and patients of our drug products as a safe and effective treatment, as well as acceptance by consumers of our aesthetics ingredient products as a novel treatment, (v) the timing of market introduction of our product candidates as well as competitive drugs, (vi) the amount of upfront costs or training required for physicians to administer our product candidates, (vii) the availability of adequate coverage, reimbursement and pricing by third-party payers and government authorities, (viii) relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies, (ix) adverse publicity about our products or favorable publicity about competitive products, and (x) the effectiveness of our sales and marketing efforts.

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

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

We have established a GMP-compliant production facility in Suzhou. Our existing and future manufacturing facilities are required to obtain and maintain regulatory approvals. They are also subject to ongoing, periodic inspection by the NMPA, the U.S. FDA or other comparable regulatory authorities to ensure compliance with GMP regulations. We may be unable to consistently comply with, or adequately document compliance with, applicable GMP regulations or other regulatory requirements, and regulatory inspections may identify material deficiencies that require remediation, re-inspection, or further corrective actions, which can be time consuming and costly. Failure to obtain and maintain such regulatory approvals of our manufacturing facilities may subject us to sanctions such as fines, injunctions, penalties, suspension of clinical trials, refusal of regulatory authorities to grant marketing approval of our product candidates, delay, suspension or withdrawal of issued approvals, supply disruptions, seizures or recalls of our product candidates, operating restrictions and criminal prosecutions, any of which may have an adverse effect on our business.

If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue.

Our commercialization strategies for different products, such as oncolytic immunotherapy candidates and engineered exosome candidates (specifically for topical treatments), may need to be distinct and tailored to each market segment. A failure to develop and implement effective and differentiated marketing strategies for these products could result in unsuccessful product launches or limited market penetration. Further, as a company rooted in China, we have limited experience in

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overseas markets. This increases the risk of failure in marketing our engineered exosome products, and potentially other products, outside of China, as we may not fully understand or effectively respond to the local regulatory, cultural, or competitive environments.

In the long term, we may determine to develop and expand our in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. There can be no assurance that we will be able to successfully develop and maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaboration partners to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

The illegal and/or counterfeit pharmaceutical and aesthetics products may reduce demand for our product candidates, which could have a negative impact on our reputation and business.

The illegal import of similar or competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved product candidates and, in turn, may adversely affect our sales and profitability in the jurisdictions where we plan to commercialize our product candidates. Illegal imports of prescription drugs may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our drugs and exert commercial pressure on pricing within one or more markets. Any future legislation or regulations that increase consumer access to lower priced imported medicines where we operate could have a material adverse effect on our business.

Certain pharmaceutical and aesthetics products distributed or sold in our target markets may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their usage or manufacturers. Since counterfeit pharmaceutical and aesthetics products in many cases have very similar appearances compared with the authentic pharmaceutical and aesthetics products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved product candidates. Furthermore, reputation and business could suffer harm as a result of counterfeit pharmaceutical and aesthetics products sold under our or our collaboration partners’ brand name(s).

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

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors’ drugs and product candidates. Any such guidelines, recommendations or studies that reflect negatively on our product candidates, either directly or indirectly relative to our competitive product candidates, could result in current or potential decreased use of, sales of, and revenues from one or more of our product candidates. Furthermore, our success depends in part on our ability to educate healthcare providers and patients about our product candidates, and these education efforts could be rendered ineffective by, among other things, third parties’ guidelines, recommendations or studies.

The national, provincial and other third party drug reimbursement practices and drug pricing policies or regulations are evolving from time to time, which could impact our business.

The regulations that govern regulatory approvals, pricing and reimbursement for medical products vary widely from country to country. Our ability to commercialize any product 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, private health insurers and other organizations. Government authorities and third-party payers may control costs by limiting coverage and the amount of reimbursement for particular medications.

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The national or local medical insurance catalogs, as well as drug reimbursement lists are reviewed and updated regularly. There can be no assurance that any of our future approved drugs will be included in the national, provincial or local medical insurance catalogs. Novel drugs similar to our product candidates have historically been more limited on their inclusion in such medical insurance catalogs. Even if our product candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates.

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effective data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients may be unlikely to use any of our future approved products if no coverage is provided or reimbursement is inadequate to cover a significant portion of the cost of the products. Because some of our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any approved product candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

There may be delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product candidates are approved by the regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved product candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Our success depends in large part on our ability to protect our proprietary technologies and product candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the product candidates and technology that we consider commercially important by filing patent applications relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we have sought patents for our core and major products. For further information on our patent portfolio, see “Business — Intellectual Property” in this document.

The patent prosecution, maintaining and protect process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. Moreover, patents may be invalidated and patent applications may not be granted, or our ownership may be challenged for a number of reasons, including the examiner’s subjective judgment, known or unknown prior art, which might lead to the lacking of novelty or an inventive step of the invention or technology, or deficiencies or defects in the patent applications. We cannot assure that all of our patent applications will be granted. It is also possible that we will fail to identify patentable subject matter of our research and development output in time to obtain patent protection. If a third party can establish that we were

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not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties whoever first filed a patent application relating to a technology, which could prevent us from using, developing, manufacturing or commercializing our product candidates or technologies without obtaining a license from such third parties.

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our product candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Our intellectual property rights in certain jurisdictions may have a lesser or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and other intellectual property rights at risk of being invalidated or interpreted narrowly and could provoke third parties to assert claims against us. Any of the foregoing could have adverse impact on our competitive position, business, financial conditions, results of operations and prospects.

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

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. Even if we successfully obtain patent protection for a product candidate, such product candidate may face competition from generic or biosimilar medications once the patent has expired. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office; thus, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product candidate exclusively, which would have a material adverse effect on any potential sales of that product candidate.

Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities will agree with our assessment of whether such extensions are available, which could materially and adversely affect our competitive position, business, financial conditions, results of operations and prospects.

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

We may become involved in lawsuits to protect or enforce our intellectual property from time to time. However, we may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly.

Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our product candidates. We may also be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed (if any in the future) patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor.

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Litigation may be necessary to defend against these and other claims challenging ownership or inventorship of our owned or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, our efforts to identify and avoid infringing on third parties’ intellectual property rights may not always be successful. Defending ourselves against third parties’ intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team’s attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

In the event that third parties assert infringement claims against us, there is no assurance that the outcome would be in our favor, as whether a product candidate or technology infringes on third parties’ intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge or invalidate a third-party intellectual property right may be high. If we were found by courts or other competent authorities to have infringed on the patent or other intellectual property rights of third parties, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing our product candidates, or at least delay the development or commercialization process. Even if the litigations or other proceedings are resolved in our favor, our involvement in such proceedings may attract publicity, thereby having a substantial adverse effect on our reputation and brand name.

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

Our trademark registrations and trademark applications may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any currently pending trademark applications or any trademark applications we may file in the future will be approved. Opposition or cancelation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially and adversely affect our business.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

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

In addition to our issued patents and pending patent applications, we rely on our trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our product candidates.

However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Any of the parties with whom we enter into confidentiality agreements may breach the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our product candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable.

Furthermore, our employees, consultants and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of them may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights.

Intellectual property laws and regulations are subject to change, which could impact the value of our intellectual property and impair the intellectual property protection of our product candidates.

Obtaining and enforcing patents in the pharmaceutical industry involves technological and legal complexity, which is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the United States or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents and diminish our ability to protect our intellectual property rights.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the applicable authorities, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights. Any of the foregoing could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

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Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to non-compliance with those requirements.

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

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

The intellectual property legal systems vary across different countries and regions, introducing uncertainty to the protection of corporate intellectual property. The intellectual property protection in various countries has its limitations, which may be insufficient to fully safeguard our business or enable us to maintain a competitive edge. For example, others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights. It is possible that our pending patent applications or those that we may own in the future will not lead to issued patents, and patents that may be issued from our pending patent applications can not provide us with any competitive advantages, or are held invalid or unenforceable. Also, our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets. We may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sales of the related product, the commercial value of our patents may be limited.

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

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability.

Investment in biopharmaceuticals entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We incurred losses and net operating cash outflows in each period since our inception. In 2023, 2024 and 2025 and the five months ended May 31, 2026, we recorded loss for the year/period of RMB481.8 million, RMB523.8 million, RMB518.9 million and RMB137.3 million, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from administrative expenses associated with our operations. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue to expand our research and development of our product and product candidates, as well as to enhance our sales and marketing efforts.

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

As of December 31, 2023, 2024 and 2025 and May 31, 2026, we had net liabilities of RMB1,274.1 million, RMB1,804.8 million, RMB2,276.3 million and RMB2,366.1 million, respectively, and had net current liabilities of RMB1,297.7 million, RMB1,866.2 million, RMB2,309.8 million and RMB2,390.6 million, respectively, primarily due to our convertible redeemable Preferred Shares issued to [REDACTED] investors, and because our convertible redeemable Preferred Shares issued to [REDACTED] Investors are recorded as current liabilities. A net liabilities position and net current liabilities position can expose us to liquidity and financial risks. This in turn could require us to seek financing from external sources such as debt issuance and bank borrowings, which may not be available on terms favorable or commercially reasonable to us or at all. See also “— We may need to obtain additional financing to fund our operations even if we consummate the [REDACTED], and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary product candidates.”

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

We recorded net cash used in operating activities of RMB94.3 million, RMB88.9 million, RMB104.7 million and RMB33.8 million in 2023, 2024 and 2025 and the five months ended May 31, 2026, respectively, primarily attributable to our loss before taxation. For a more comprehensive discussion of our liquidity and capital resources, see “Financial Information — Liquidity and Capital Resources — Net Cash Used in Operating Activities” for further details. We cannot guarantee that prospective business activities of our Group and/or other matter beyond our control will not adversely affect our operating cash flows and lead to net operating cash outflows in the future. If we encounter long-term and continuous net operating cash outflow in the future, we may not have sufficient working capital to cover our operating costs, and our business, financial position and results of operations may be materially and adversely affected.

Uncertainty over the fair value changes in our Shares and related valuation may materially affect our financial performance and results of operations.

As of December 31, 2023, 2024 and 2025 and May 31, 2026, our convertible redeemable Preferred Shares amounted to RMB1,510.3 million, RMB1,956.1 million, RMB2,276.0 million and RMB2,314.8 million, respectively. In addition, the fair value change of the Preferred Shares shall be charged to the fair value change on convertible redeemable Preferred Shares in profit or loss, and therefore, directly affecting our financial performance and results of operations. The estimated changes in fair value involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the financial liabilities valuation has been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect the actual fair value of these financial liabilities and result in significant fluctuations in profit or loss from year to year, which could materially and adversely affect our financial performance and results of operations. The financial liabilities of such Preferred Shares will be derecognized and credit to equity as a result of the automatic conversion into Ordinary Shares upon the [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares.

We may need to obtain additional financing to fund our operations even if we consummate the [REDACTED], and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary product candidates.

During the Track Record Period, we funded our operations primarily through equity and debt financing and revenue from our out-licensing and collaboration agreements. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage product candidates, continue the research and development of our preclinical stage product candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future product candidates. In addition, if we obtain regulatory approvals

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for any of our product candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. We may also incur expenses as we create additional infrastructure to support our operations as a [REDACTED] company. Accordingly, we may need to secure substantial additional funding in connection with our continuing operations through public or private equity [REDACTED], debt financing, collaborations or licensing arrangements or other sources.

We expect to fund our future operations primarily with existing cash and cash equivalents, revenue from our out-license and collaboration agreements, and [REDACTED] from the [REDACTED]. Upon the successful commercialization of one or more of our product candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. If we are unable to raise [REDACTED] when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

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

During the Track Record Period, we recognized RMB16.1 million, RMB8.2 million, RMB4.4 million and RMB2.2 million of government grants in other net income in the years ended December 31, 2023, 2024 and 2025 and the five months ended May 31, 2026, respectively. Some of the government financial incentives, grants or funding are granted on a project-by-project basis and/or are subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements, completion of the specific projects therein, and compliance with the conditions imposed including but not limited to maintaining operations or physical facilities. We cannot guarantee that we will satisfy all relevant conditions. If we fail to satisfy any such condition upon a corporate change or other difficulties to meet the conditions, we may be deprived of or be asked to return the relevant incentives, funding, and/or government grants, or we may be asked to repay our debt obligations early, if any, as the case may be.

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

The Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar, at times significantly and unpredictably. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the Hong Kong dollar or U.S. dollar in the future.

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

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RISKS RELATING TO OUR OPERATIONS

Any failure to comply with applicable regulations and industry standards or obtain or renew certain approvals, various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC, the U.S. and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our CROs’ failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations. For example, if we or our CROs were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including being required to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations.

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

As a biotechnology company, our success is highly dependent on the expertise, leadership and vision of a limited number of key research and development personnel, in particular our founder, chairperson of our Board and chief executive officer of our Group, Dr. Grace Guoying Zhou. Dr. Zhou has played, and is expected to continue to play pivotal roles in shaping our research and development strategies, driving scientific innovation and overseeing the execution of our core business initiatives. Her deep industry knowledge, technical expertise and extensive experience have been instrumental to our achievements during the Track Record Period, and we expect her continued involvement to be critical to our future prospects.

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

As we have significantly increased the size and capabilities of our organization since our inception, we may experience difficulties in managing our growth.

Since our inception, we have made significant strides in expanding our organization and enhancing our operational capabilities. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of

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business opportunities, loss of employees and reduced productivity among remaining employees. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially adversely affect our business, financial condition, results of operations and prospects.

We may engage in acquisitions or strategic partnerships, which may increase our capital requirements, cause dilution for our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including but not limited to, (i) increased operating expenses and cash requirements, (ii) the assumption of additional indebtedness or contingent or unforeseen liabilities, (iii) the issuance of our equity securities, (iv) assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, and (v) the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense. According to the Anti-Monopoly Law of PRC (《中華人民共和國反壟斷法》) and the Provisions of the State Council on Thresholds for Prior Notification of Concentrations of Undertakings (《國務院關於經營者集中申報標準的規定》), issued by the State Council of the PRC (the “**State Council**”), the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be filed in advance to the State Administration for Market Regulation of the PRC (“**SAMR**”) when the threshold is crossed and such concentration shall not be implemented without the clearance of prior filing.

We face risks related to natural disasters, health epidemics and outbreaks of contagious diseases, and other factors beyond our control.

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in which we operate our business could materially disrupt our business and operations. These uncertain and unpredictable factors include, but are not limited to, adverse effects on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners.

We are subject to the risks of doing business globally. Disruptions in the financial markets and economic conditions could affect our ability to raise [REDACTED].

International markets are an important component of our growth strategy. We will continue to seek licensing and co-development opportunities with global MNCs and expand our global clinical programs. For more details, see “Business — Our Strategies.” However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including but not limited to changes in a specific country’s or region’s political and cultural climate or economic condition, unexpected changes in laws and regulatory requirements in local

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jurisdictions, challenges to develop an international sales, marketing and distribution organization, significant adverse changes in local currency exchange rates, and business interruptions resulting from geo-political actions and cultural climate or economic condition.

Furthermore, global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors, including extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.

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

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

We maintain industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. Although we maintain insurance coverage for adverse events in clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. In line with general market practice, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Any failure to comply with the PRC regulations regarding mandatory social insurance and housing provident fund contributions may subject us to fines and other legal or administrative sanctions.

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) which was last amended on December 29, 2018 and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and contribute social insurance premium for its employees. Any failure to open social insurance registration account may trigger an order of correction where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium within a specified period of time, and the competent authority may further impose fines or penalties. According to the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), as amended in 2002 and 2019, the relevant housing fund authority may order an enterprise to pay outstanding contributions within a prescribed time limit.

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From time to time, the Supreme People’s Court may also issue judicial interpretations of existing laws and regulations relating to contributions to the social insurance and the housing provident funds. For example, according to the Supreme People’s Court’s Interpretation (II) on Several Issues Concerning the Application of Law in Labor Dispute Cases (《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)》) promulgated by the Supreme People’s Court on July 30, 2025 and effective on September 1, 2025, where an employer fails to pay social insurance premiums in accordance with the law, and the employee requests to terminate the employment contract and for the employer to pay economic compensation, the people’s court shall uphold such requests in accordance with the law. Where an employer, after making up the social insurance contributions in accordance with the law under the circumstances stipulated in the preceding sentence, requests the employee to return the social insurance compensation already paid, the people’s court shall support such request in accordance with the law. The introduction of new judicial interpretations or changes in regulatory guidance in the future may result in certain aspects of our operations being deemed not fully compliant with evolving labor laws and regulations. As of the Latest Practicable Date, (i) we had not entered into any written agreements with any of our employees under which employees undertook not to participate in social insurance schemes; (ii) no labor disputes or legal proceedings concerning social insurance or housing provident fund contributions had been raised against us; and (iii) even if any relevant labor disputes were to arise, such disputes would only involve economic compensation, the amount of which would not adversely affect our business and financial condition in all material respects. Based on the foregoing, our Directors are of the view, and our PRC Legal Advisors concur, that the implementation of the Interpretation II is unlikely to have any material adverse impact on our business, results of operations, or financial condition.

In addition, during the Track Record Period, we engaged third-party human resources agencies to make contributions to social insurance and housing provident funds for certain of our employees (“**Third Party Arrangement**”). During the Track Record Period and up to the Latest Practicable Date, the estimated aggregate social insurance and housing provident funds contributions through the Third Party Arrangement amounted to approximately RMB4.0 million and RMB1.9 million, respectively. As of the Latest Practicable Date, one third-party human resources agency continued to provide such contributions for eight of our employees, all of whom are employed by Immvira Shenzhen. As advised by our PRC Legal Advisor, under applicable PRC laws and regulations, for such Third Party Arrangement: (i) for social insurance, the relevant authorities in mainland China may require us to rectify the arrangement within a prescribed time limit. If we fail to rectify the situation within the stipulated period, a fine ranging from one to three times the amount of the relevant contributions may be imposed, with a maximum potential penalty of RMB12.0 million; and (ii) for housing provident funds, the housing provident fund management center may order us to rectify within a prescribed time limit. If the Company fails to comply, a fine ranging from RMB10,000 to RMB50,000 may be imposed per entity, with a maximum potential penalty of RMB50,000. While regulatory fines, outstanding contributions, late fees or rectification orders that may be imposed in connection with social insurance and housing provident funds may have an impact on our financial condition, given the relatively small amount involved, we do not expect any material impact on its operations or financial results.

We have obtained the compliance certificates from the relevant government authorities in charge of social insurance and housing provident fund that, during the Track Record Period, there was no record indicating that we violated any laws, regulations or rules in relation to social insurance and housing provident fund. As advised by our PRC Legal Advisor, considering relevant regulatory policies and the facts stated above and the confirmations we have received from the relevant PRC authorities, the likelihood that our PRC subsidiaries will be subject to centralized collection of historical direct shortfalls is remote. However, the relevant government authorities may take a different view in the future and there is no assurance that our historical and current practice with respect to the contribution of social insurance plans will at all times be deemed in full compliance with relevant laws and regulations in mainland China by government authorities. In the event of any such non-compliance, we may be required to pay any shortfall in social insurance contributions and to pay penalties if we fail to do so.

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As the laws and policies related to social insurance and housing provident fund may continue to evolve, we cannot assure you that our employment policies and practices will always be regarded as fully complying with the relevant laws and regulations in China. We cannot guarantee that we would not be required to pay any shortfall or be subject to any penalties or fines, any of which may have a material and adverse effect on our business and results of operations.

Increased labor costs could slow our growth and affect our operations.

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, production, quality control and other personnel. We face intense competition in recruiting and retaining qualified personnel, as competitors are competing for the same pool of qualified personnel and our remuneration packages may not be as competitive as those of our competitors. Increasing market competition may cause market demand and competition for qualified employees to intensify. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially adversely affect our results of operations.

We are subject to environmental protection, health and safety laws and regulations, and if we or our CROs, CDMOs and other business partners fail to comply with these laws and regulations, we could be subject to fines, penalties, or other adverse consequences or incur costs that could have a material adverse effect on our business.

We and certain third parties we work with, such as our CROs, CDMOs and business partners, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. For instance, during the Track Record Period, we did not declare occupational hazard projects, conducted testing of occupational disease hazard factors, or evaluated and organized the acceptance check of facilities for the prevention and control of occupational diseases according to PRC regulations. However, we have later completed the required declarations for occupational hazard projects in accordance with PRC laws and regulations. Our PRC Legal Advisor is of the view that, based on the facts that (a) we have not been investigated, warned, fined, or subjected to any enforcement measures or penalties for failure to declare occupational hazard projects, (b) we have obtained written confirmation from the relevant government authority in charge of occupational disease prevention that, during the Track Record Period, we are not subject to any administrative penalties by such authority, and (c) we have completed the required declarations to rectify the previous matter, and such matter has not had, and is not expected to have, any material adverse impact on the Group’s operations. Accordingly, the Company does not expect any material penalties or negative consequences to arise from this matter.

Our operations may involve the use of hazardous and flammable materials, we cannot eliminate the risk of contamination or injury from these materials, which could result in significant liabilities, fines or penalties that may exceed our resources, and we do not maintain insurance for environmental liability, toxic tort claims or employee injuries arising from such exposure. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations, which may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees, principal investigators, consultants and commercial partners.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

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

Despite the implementation of security measures, our information technology systems and those of our CROs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, and the further development of our product candidates could be delayed.

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

Any negative publicity concerning us, our affiliates, our Shareholders, Directors, officers, employees and business partners, management, even if untrue, could adversely affect our reputation and business prospects. In addition, to the extent our Shareholders, Directors, officers, employees and business partners were in compliance with any laws or regulations or involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity. In addition, any negative publicity about us could adversely affect our ability to maintain our existing collaboration arrangements or attract new collaboration partners, and we may not be able to diffuse such negative publicity to the satisfaction of our investors.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We work with various third parties to develop our product candidates. If these third parties do not successfully carry out their contractual duties, fail to comply with regulatory requirements, or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, and our business could be materially harmed.

We have relied on and plan to continue to rely on third-party CROs and other third parties to monitor and manage data for some of our ongoing preclinical and clinical programs. We rely on these parties for the execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities.

The CROs we engage may not always perform to our standards, may not produce results in a timely manner or may fail to perform at all. If we or any of our CROs fail to comply with the applicable GCP, GLP, cGMP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance the regulatory authorities will determine that our clinical trials comply with all the applicable requirements. Failure to comply with these regulations may lead us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Because we rely on third parties, our internal capacity to perform these functions is limited. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. In addition, the use of third-party service providers requires us to disclose our proprietary information or confidential information concerning the subjects enrolled in our clinical trials to these third parties, which could increase the risk that such information will be misappropriated.

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In addition, we may not be able to enter into arrangements with alternative CROs and other third parties in a timely manner or do so on commercially reasonable terms, if our existing relationships with these third parties terminate. Switching or adding CROs and other third parties involves additional cost and delays, which can materially affect our ability to meet our desired clinical development timelines. Any of such delays or challenges may have a material adverse effect on our business, financial condition and prospects.

We may rely on third parties to manufacture our products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our clinical development and commercialization needs. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels.

To date, we have relied primarily on third-party service providers, including CDMOs, to manufacture our product candidates. See “Business — Manufacturing — Collaboration with CDMOs” for details. Going forward, we intend to continue to engage third-party CDMOs to manufacture our product candidates for our research and development activities and commercial sales, while gradually establishing our in-house manufacturing capabilities. Our reliance on third-party CDMOs exposes us to certain risks, including, but not limited to, risks arising from the limited availability and capacity of qualified CDMOs, regulatory oversight and compliance requirements imposed by the NMPA, the FDA or other comparable authorities, potential failures to meet required timelines, quantities or quality standards, and inadequate performance of manufacturing or logistical obligations. In addition, our CDMOs may misuse or fail to adequately protect our intellectual property or proprietary information, infringe third-party intellectual property rights, terminate their agreements with us, or experience supply interruptions due to regulatory actions, natural disasters or other events beyond our control, any of which could disrupt our operations or adversely affect our business. See also “— Risks Relating to the Manufacturing and Commercialization of our Product Candidates — The manufacturing of biopharmaceutical products is a complex process, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.”

In addition, during the Track Record Period, we and our CDMOs relied on third parties to supply certain raw materials and products used in our research and development and clinical trials. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our product candidates. Our reliance on third-party suppliers for raw materials exposes us to risks of supply disruption, capacity constraints and delays, particularly as our demand for such materials increases with the expansion of our research, development and commercialization activities, any of which could impair our operations or the development of our product candidates. In addition, the quality of raw materials and products manufactured by our CDMOs depends significantly on the effectiveness of our and our CDMOs’ quality control and quality assurance systems, and any failure or deterioration of such systems or standard operating procedures could result in products being unsuitable for use, jeopardize regulatory approvals or licenses, and adversely affect our market reputation and relationships with business partners, which may have a material adverse effect on our business, financial condition and results of operations.

We are exposed to risks related to concentration of suppliers.

Purchases from our five largest suppliers in each year/period during the Track Record Period accounted for 64.4%, 58.3%, 51.9% and 48.9% of our total purchase amount, respectively, in the years ended December 31, 2023, 2024 and 2025 and the five months ended May 31, 2026, respectively. However, we cannot assure you that these suppliers will continue to provide supplies and services at prices and on terms and conditions acceptable to us. Our reliance on our top five suppliers may also expose us to the risk of unexpected price increases for purchases, or shortage in supply of raw materials and services. In such a situation, our business, financial condition and results of operations may be materially and adversely affected.

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We have only limited customers during the Track Record Period.

We are a clinical-stage biotechnology company and have not commercialized any of our product candidates during the Track Record Period. As a result, we had a limited number of customers, and our revenue was derived from out-licensing and collaboration arrangements with our respective partners. In 2023, 2024 and 2025, we generated revenue from two partners, and we did not have any customers in the five months ended May 31, 2026. Please refer to the section headed “Business — Customers” for more details. Given our reliance on two out-licensing and collaboration partners, there is no assurance that we will be able to secure new partners in the future. If any of these key partners chooses to terminate their collaboration, or if we are unable to secure new partners in a timely manner, our business, financial condition, and results of operations may be materially and adversely affected.

We have entered into collaboration with our partner and may seek further collaboration opportunities and strategic alliances or enter into licensing arrangements in the future, but we may not realize the benefits of such collaboration, alliances or licensing arrangements.

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our drug development, manufacturing and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. To date, we have entered into several licensing and collaboration arrangements with reputable industry players and institutions worldwide. See “Business — Collaboration Agreements” for details.

Our results of operations have been, and may continue to be, affected by our collaboration and licensing arrangements. During the Track Record Period, all of our revenue was generated from such arrangements. Collaboration and licensing agreements involving our product candidates are subject to various risks, which have historically contributed a significant portion of our revenue.

Our collaborators generally have significant discretion over the level of efforts, resources, funding and priorities they apply to a collaboration, and may delay, modify, discontinue or terminate development, clinical trials or commercialization activities due to changes in strategic focus, funding availability, regulatory considerations or other external factors. In addition, milestone payments and royalties are contingent upon the achievement of specified regulatory, development and commercialization targets, and collaborators may independently develop competing products, co-own relevant intellectual property or otherwise act in ways that may limit our control, expected economic returns or competitive position. Disputes may arise between us and a collaborator including potential deadlocks within a joint steering committee (“JSC”) we established with the collaborators, that cause a delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources. Furthermore, our collaboration and licensing arrangements may be adversely affected by intellectual property protection issues, cross-border data transmission restrictions, geopolitical tensions, trade policies or export controls, any of which could impair the expected benefits of such collaborations and have a material adverse effect on our business, financial condition and results of operations. As a result, collaboration and licensing arrangements are inherently uncertain, and we may not achieve the expected outcomes, synergies or timing, and may incur increased costs, operational disruption or diversion of management attention. We also face competition in identifying and securing suitable collaboration partners, and negotiations may be time-consuming and complex. Entering into collaboration arrangements may require us to relinquish a degree of control over the development and commercialization of our product candidates.

In addition, under certain of our collaboration agreements, key decisions regarding the research, development or commercialization of our product candidates are made by a JSC composed of representatives from both us and our collaboration partners. In the event of a deadlock within the JSC, the final decision may be made in favor of our collaboration partners rather than us. This could result in decisions that are not aligned with our interests or strategies, and may adversely affect the progress, direction or timing of our product development programs. If we are unable to reach agreements with suitable collaborators in case of disputes or deadlocks within a JSC on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its

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development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expenses. If we fail to enter into collaboration and licensing arrangements or face difficulties in securing adequate reimbursement from existing collaborators, or do not have sufficient funds or expertise to undertake the necessary development, manufacturing and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects. If the JSC deadlock results in decisions that delay, limit or otherwise negatively impact our product development, our business, financial condition, results of operations and prospects could be materially and adversely affected.

If our business partners fail to maintain the necessary licenses for the development, manufacturing and commercialization of our products, our business could be materially affected.

Our business partners, such as CROs, CDMOs and suppliers, on whom we may rely on to develop, manufacture, market, sell and distribute our product candidates, may be subject to requirement of obtaining and maintaining necessary permits, licenses and certificates in their operations. Our business partners may also be subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. If our business partners fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Any changes in the standards used by governmental authorities in considering whether to renew or reassess our business partners’ licenses, permits and certifications, as well as enactment of any new regulations that may restrict the operation of our business partners’ operations, may also decrease our revenue and increase our costs, which in turn could materially and adversely affect our business, financial condition and results of operations.

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

We cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, KOLs, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to the successful development and marketing of new products. Situations including, but not limited to, cease of their roles or their collaboration with us, inaccuracy of their market insights and perceptions, and change of their business or practice focus may adversely affect our business, financial condition and results of operations.

RISKS RELATING TO GOVERNMENT REGULATIONS

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

All jurisdictions in which we operate or intend to operate our business regulate the research, development, manufacturing and commercialization of biopharmaceutical products. We intend to implement a global development strategy and intend to focus our activities in the major markets including the U.S. and China, where regulatory requirements governing product development and approval, manufacturing, and marketing, sales and distribution are stringent and subject to change. Compliance with these regulatory regimes requires us to obtain and maintain various approvals, licenses and permits and to devote substantial time and financial resources. Differences and changes in regulatory requirements across jurisdictions may increase compliance costs and complexity. If we fail to obtain or maintain the required approvals or comply with applicable laws and regulations at any stage of product development, approval or after commercialization, regulatory authorities may impose

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sanctions, such as denial or withdrawal of approvals, license revocation, clinical holds, product recalls, suspension of operations, fines or other civil or criminal penalties, any of which could have a material and adverse effect on our business and prospects.

In many countries or regions where a drug is intended to be ultimately sold, including China, the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. For example, we may need to obtain clearance from the NMPA or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, and file an NDA, a BLA or other similar applications to seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects.

The regulatory approval processes relating to the marketing of our product candidates are lengthy, time-consuming and can be changed. If we are unable to obtain without undue delay any regulatory approval for our product candidates in our targeted markets, our business may be substantially harmed.

Generally, approval from the NMPA and FDA take many years to obtain, following the commencement of preclinical studies and clinical trials. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. Additional time, effort and expense may be required to bring our product candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

Our product candidates could fail to receive the regulatory approval of the NMPA, the FDA or a comparable regulatory authority for many reasons, including disagreements regarding the design, conduct or interpretation of our preclinical studies or clinical trials, failure to demonstrate sufficient safety, efficacy or potency for the proposed indication, failure to achieve the required level of statistical significance, or insufficient data to support the submission or approval of an NDA, BLA or other regulatory filings. In addition, our product candidates or manufacturing facilities may fail to pass GCP or cGMP inspections, clinical site audits or other regulatory reviews, or regulatory authorities may identify deficiencies in our manufacturing processes or research data. Changes in regulatory policies, scientific standards or technological requirements may also render our existing data or development approach inadequate for approval.

The NMPA, the FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a product candidate with an indication that is not desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our product candidates.

We from time to time conduct clinical trials for our product candidates at sites in China or other regions outside the U.S. as part of a global MRCT, while FDA or comparable foreign regulatory authorities may not accept data from such trials.

We from time to time conduct clinical trials for our product candidates at sites in China or other regions outside the U.S. as part of a global MRCT, and may continue to do so in the future. The acceptance of trial data from clinical trials conducted outside the U.S. by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the U.S. are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized

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competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Additionally, the FDA’s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many regulatory bodies, such as the NMPA, have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. Currently, we are primarily subject to numerous PRC laws and U.S. federal and state laws governing data protection and privacy.

The PRC authorities promulgated a series of laws and regulations governing the various aspects of information security, data collection and privacy protection, including, among others, the Cybersecurity Law of the PRC, the Provisions on Protection of Personal Information of Telecommunication and Internet Users, the Cybersecurity Review Measures, the Data Security Law of the PRC, and the Personal Information Protection Law of the PRC.

Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual prior consent shall be obtained, unless otherwise specified. Further, any data processing activities that are in relation to the sensitive personal information are not allowed, unless such activities have a specific purpose and are highly necessary, and unless strictly protective measures have been taken and separate consent has been obtained from the individuals involved. In addition, certain industry-specific laws and regulations affect the collection and transfer of data in China. The Regulations on the Administration of Human Genetic Resources of the PRC or the HGR Regulation, was promulgated by the State Council in May 2019 and further amended in May 2024. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China’s human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China’s human genetic resources after satisfaction of all regulatory requirements, such as (i) China’s human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China’s human genetic resources information being provided after required security review, filing and information backup procedures have been gone through. In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which became effective in April 2021. The Biosecurity Law of the PRC reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China’s human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws.

Our use of China’s human genetic resources arises in the ordinary course of our clinical research and is conducted in accordance with the PRC Personal Information Protection Law, the Administrative Regulations on Human Genetic Resources (as amended), the Biosecurity Law, and Good Clinical Practice. We conduct international scientific research collaborations involving human genetic resources only through qualified PRC clinical institutions, obtain the required ethics approvals, and complete the

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requisite approvals with the competent authorities before initiation. After a study is initiated by the site, the protocol is reviewed by the institutional ethics committee; following approval, the site’s human-genetic-resources administration office completes the filing through the HGR service system, and participants sign informed consent forms that have been reviewed/record-filed with the authority and that clearly disclose international-cooperation use, risks, and withdrawal rights. Sampling (such as whole blood, serum, and tissue sections) and the generation of associated data (including safety laboratories such as hematology and chemistry, pharmacokinetic exposure, and viral shedding) are performed by site research nurses in accordance with the approved protocol; samples are safeguarded on site by clinical research coordinators and transported under cold-chain conditions to qualified third-party laboratories consistent with protocol and regulatory requirements. We maintain strict controls over the retention and use of samples and data. Safety-testing data are destroyed upon issuance of results; samples used for pharmacokinetic and other protocol-specified analyses are destroyed after testing, and any backup samples are destroyed after marketing authorization of the relevant product. We do not store samples long-term and do not use samples outside the approved protocol. Where international cooperation involves human genetic resources, we conduct such cooperation through qualified PRC institutions and complete the required approvals; where applicable, cross-border provision of human genetic resources information (not materials) follows the requisite security review, filing, and information backup procedures. These practices reflect our ongoing efforts to comply with mandatory legal and regulatory requirements while advancing our clinical programs. The interpretation and implementation of the HGR Regulation and the related laws and regulations may vary from time to time. Given such circumstance, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC and other applicable laws in our utilizing of and dealing with China’s human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation and the Biosecurity Law of the PRC and the applicable laws and regulations.

Numerous U.S. federal and state laws and regulations relate to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, known as “protected health information,” and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties and could harm our reputation and our ability to compete.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers including those arising from our own operations and those of third-party institutions, principal investigators, hospitals, CROs and other service providers involved in our clinical trials may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. In addition, we cannot ensure that such third parties will always comply with applicable data protection requirements or our internal measures, and any leakage, misuse or unauthorized disclosure of patient or other personal data by us or our partners may expose us to regulatory investigations, audits, inquiries, whistleblower complaints, class action litigation, fines, penalties, loss of export privileges, reputational harm and other civil or criminal liabilities. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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We are subject to registration, review and other requirements of the regulatory authorities for cross-border sales or licensing of technology as well as operations related to genetics and data safety.

Under the Regulations on Administration of Imports and Exports of Technologies promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts, issued by the Ministry of Commerce of the PRC (“MOFCOM”) in February 2009, specify registration requirements related to the import and export of technology. We may in the future enter into agreements with CROs in the United States for their technical support to assist us with the development of individual product candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers may be required to be registered with applicable governmental authorities. We are also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we are required to obtain approval from the Office of Human Genetic Resources Management under the Ministry of Science and Technology who will conduct genetics and data safety review. There is no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which provides that enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the government authority is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our research and development of product candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of product candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects.

On July 7, 2022, the Cyberspace Administration of China published the Measures for Security Assessment of Data Export, which took effect on September 1, 2022. It specifies the circumstances in which data processors exporting data are required to apply for outbound data transfer security assessment with the Cyberspace Administration of China, including the outbound data transfer of important data. In addition, according to the Measures for Standard Contract for Outbound Transfer of Personal Information issued by the Cyberspace Administration of China on February 22, 2023, and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall apply for filing within 10 working days after the standard contract enters into effect. On March 22, 2024, the Cyberspace Administration of China issued the Provisions on Facilitating and Regulating Cross-border Data Flows. It provides that a data handler that is not a critical information infrastructure operator will be exempted from declaring for security assessment for outbound data transfer, signing a standard contract with overseas recipient, or passing the personal protection certification, if such data handler accumulatively transfers overseas personal information (excluding sensitive personal information involving at least 10,000 individuals) of less than 100,000 individuals since January 1 of the relevant year.

Cross-border data transfer across different jurisdictions may also be limited if we fail to comply with relevant requirements, such as obtaining authorization from subjects regarding the use, transfer and retrieval of their personal information or data and adopting measures to ensure the safety of personal information or data in the transfer. Also, cross-border transfer of personal data by its nature is subject to general data privacy regulations in various jurisdictions, and thus any failure to comply with data privacy protection may lead to a restriction of transferring our data across different jurisdictions.

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Even if we receive regulatory approval for our product candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If the NMPA, the FDA or a comparable regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, storage, distribution, adverse event reporting, advertising, promotion, sampling, recordkeeping and post-marketing studies for the drug will be subject to extensive and ongoing or additional regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any chemistry, manufacturing and controls, variations, continued compliance with GMPs, cGMPs, GCPs, good storage practices and good vigilance practices and potential post-approval studies for the purposes of license renewal.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. Any such issues could result in regulatory actions, including marketing or manufacturing restrictions, recalls, clinical holds, refusal, suspension or revocation of approvals, seizure or detention of products, or the imposition of civil, administrative or criminal penalties.

Regulatory authorities also strictly regulate the marketing, labeling, advertising and promotion of drugs, including prohibitions on off-label promotion, and any non-compliance or related investigation could expose us to significant liability, require substantial management time and resources and result in negative publicity. Changes in regulatory policies or requirements, or our failure to maintain compliance, could prevent, limit or delay approvals, result in the loss of existing approvals and materially and adversely affect our business, financial condition, results of operations and prospects.

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

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and the United States. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with governments.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

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Furthermore, we are subject to anti-bribery laws that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to the Foreign Corrupt Practices Act, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, business restrictions or exclusion from participation in governmental programs. We may also be adversely affected by investigations or allegations of non-compliance, regardless of their ultimate outcome.

Changes in U.S. and international trade policies may cause significant disruptions to our product candidate manufacturing and other operations.

We are susceptible to constantly changing international economic, regulatory, social and political conditions and local conditions in foreign countries and regions. China’s political relationships with foreign countries and regions may affect the prospects of our relationships with third parties, such as business partners, suppliers and future customers. Any tensions and political concerns between China and the relevant foreign countries or regions may cause a decline in the demand for our future products and adversely affect our business, financial condition, results of operations, cash flow and prospects. Rising trade and political tensions could reduce levels of trade, investments, technological exchanges and other economic activities between China and other countries and regions, which would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies. Furthermore, retaliatory tariffs or other trade restrictions may impact our ability to effectively compete in certain markets, particularly the U.S., which could hinder our growth and long-term prospects.

Any failure by the Shareholders or beneficial owners of our Shares to make required applications and filings pursuant to regulations relating to offshore investment activities could restrict our ability to distribute profits and subject us to liabilities.

Under PRC foreign exchange regulations, including SAFE Circular 37 and related rules, PRC residents are required to complete registration or amendment filings in connection with their direct or indirect offshore investment activities. If such registration or amendment is not completed in a timely manner, our PRC subsidiaries may be prohibited from distributing profits or proceeds from capital reduction, share transfer or liquidation to us, and we may be restricted from making additional capital contributions to our PRC subsidiaries, and the relevant PRC residents or entities may be subject to penalties for violations of foreign exchange regulations. Although we are committed to complying with applicable foreign exchange laws and to facilitating compliance by our Shareholders, we may not be fully aware of the identities of all beneficial owners who are PRC residents or be able to compel their compliance. Any failure by such Shareholders or beneficial owners to comply with applicable registration requirements could adversely affect our ability to conduct cross-border fund flows and have a material adverse effect on our business and financial condition.

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

We are a holding company incorporated as an exempted company in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set

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aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends.

Dividends paid by our PRC subsidiaries to us may be subject to PRC withholding taxes.

The PRC Enterprise Income Tax Law (“**Enterprise Income Tax Law**”) and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries are expected to be subject to the PRC withholding tax at a rate of 10%.

Pursuant to the Arrangement between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income, the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of our PRC-sourced income, and it directly holds 25% or more interests in our PRC subsidiaries. On February 3, 2018, the State Administration of Taxation of the PRC (“**SAT**”) issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement, also known as Circular 9. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner. There is no assurance that the reduced withholding tax rate will be available to any of our Hong Kong subsidiaries.

We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law and become subject to tax liabilities.

Under the Enterprise Income Tax Law, an enterprise established outside the PRC with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for the PRC enterprise income tax (“**EIT**”) purposes. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. The SAT has subsequently provided further guidance on the implementation of Circular 82.

If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC EIT purposes, a number of tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to EIT at a rate of 25% on our worldwide taxable income, as well as to PRC EIT reporting obligations. Second, although under the EIT Law and its implementing rules, dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax. Finally, dividends paid by us to our non-PRC shareholders, and any gain realized from the transfer of our Shares by our non-PRC shareholders, may be treated as income derived from sources within China. As a result, dividends paid to our non-PRC resident enterprise shareholders may be subject to PRC withholding tax and gains realized by our non-PRC resident enterprise shareholders from the transfer of our Shares may be subject to PRC tax. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

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We and our Shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company.

Pursuant to the Bulletin on Issues of Enterprise Income Tax Concerning Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7, an “indirect transfer” of “PRC taxable assets,” including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC EIT. As a result, gains derived from such indirect transfer may be subject to PRC EIT. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC EIT pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. As such, the [REDACTED] of the Shares on a public stock exchange will not be subject to PRC EIT pursuant to Bulletin 7. However, the [REDACTED] of our Shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC EIT under Bulletin 7. Bulletin 7 may be determined by the tax authorities to be applicable to sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-PRC resident enterprises and PRC subsidiaries may be required to spend resources to comply with Bulletin 7 or to establish that we and our non-PRC resident enterprises should not be taxed under Bulletin 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries.

The PRC tax authorities make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment under Bulletin 7. If the PRC tax authorities make adjustments to the taxable income of the transactions under Bulletin 7, our income tax costs associated with such potential acquisitions or disposals may increase.

Our ability to utilize our revenue is subject to regulatory requirements over foreign currency conversion.

Currency conversion and remittance is subject to the relevant regulatory requirements. As a substantial majority of our future revenue is expected to be denominated in RMB, any shortage in availability of foreign currency may have an impact on the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for distributing dividends or making other payments or satisfying our foreign currency denominated obligations. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, any existing and future changes on regulations relating to currency exchange may have an influence on our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

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

In 2012, the SAFE, promulgated the Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company. Pursuant to these rules, PRC citizens and non-PRC citizens who reside in China for a continuous period of not less than one year and participate in any stock incentive plan of an overseas publicly listed company are required to register with SAFE through a domestic qualified agent, which could be the PRC subsidiaries of such overseas-listed company, and complete certain other procedures, unless certain exceptions are available. In addition, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. We and our executive officers and other employees who are PRC citizens or

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non-PRC citizens living in China for a continuous period of not less than one year and have been granted options will be subject to these regulations when our Company becomes an [REDACTED] company upon the completion of the [REDACTED]. Failure to complete SAFE registrations may subject them or us to fines or supervision measures. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees.

In addition, the State Taxation Administration of the PRC (“STA”), has issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in China who exercise share options or are granted restricted shares will be subject to PRC individual income tax. Our PRC subsidiary has obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes for those employees who exercise their share options. If our employees fail to pay or we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities.

We are subject to filings and other requirements from the CSRC or other PRC regulatory authorities for the [REDACTED] and [REDACTED] of our Shares on the Stock Exchange.

On February 17, 2023, the CSRC released Trial Administrative Measures for Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Overseas Listing Trial Measures”) and five relevant guidelines, which became effective on March 31, 2023. Pursuant to the Overseas Listing Trial Measures, PRC domestic companies which, after the overseas offering and listing, offers subsequent securities in the same overseas market or conducts offering and listing in other overseas markets (the “Future [REDACTED]”), shall complete the filing procedures of, and report relevant information to, the CSRC. See “Regulatory Overview — Regulations Relating to Overseas [REDACTED].” Based on the foregoing, for the Future [REDACTED] after the proposed [REDACTED], we are required to comply with the filing procedures of the CSRC. It is uncertain whether we can, or how long it will take us to, complete filings procedures in connection with the Future [REDACTED]. We may be subject to approval, filing or other requirements by other PRC government authorities under the PRC laws in the future. Any failure to complete the relevant procedures may have an adverse effect on Future [REDACTED].

You may experience difficulties in effecting service of legal process, enforcing foreign judgments against us or our management named in the documents.

We are a holding company incorporated as an exempted company in the Cayman Islands with substantially all of our assets located in China. In addition, a majority of our Directors and senior management personnel reside within mainland China, and substantially all of their assets are located within the PRC. Therefore, it may be difficult for [REDACTED] to directly effect service of legal process upon us or our Directors and senior management personnel in the PRC.

On January 18, 2019, the Supreme People’s Court and the Hong Kong SAR Government signed 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, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong SAR and the mainland China. On January 29, 2024, the New Arrangement was declared effective jointly by the Supreme People’s Court of the PRC and the government of Hong Kong SAR. However, the New Arrangement does not apply to certain judgments of civil and commercial matters. Furthermore, there remain uncertainties as to the outcome of any applications to recognize and enforce such judgments and arbitral awards in the PRC.

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RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] market for our Shares and there can be no assurance that an active market would develop, especially taking into account that certain of our existing Shareholders may be subject to a lock-up period, and the price and [REDACTED] of our Shares may be volatile.

Prior to the completion of the [REDACTED], there has been no public market for our Shares. There can be no guarantee that an active [REDACTED] market for our Shares will develop or be sustained after completion of the [REDACTED]. The [REDACTED] is the result of negotiations between our Company and the Overall Coordinators (for themselves and on behalf of the [REDACTED]), which may not be indicative of the price at which our Shares will be [REDACTED] following completion of the [REDACTED]. The [REDACTED] of our Shares may drop below the [REDACTED] at any time after completion of the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in the Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for our Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the Shares will not decline following the [REDACTED].

The [REDACTED] price and [REDACTED] of our Shares may be volatile and could fluctuate widely in response to factors beyond our control, including general market conditions of the securities markets in Hong Kong, Mainland China, the United States and elsewhere in the world. In particular, the performance and fluctuation of the market prices of other companies with business operations located mainly in China that have listed their securities in Hong Kong may affect the volatility in the price of and [REDACTED] volumes for our Shares. A number of China-based companies have listed their securities, and some are in the process of preparing for listing their securities, in Hong Kong. Some of these companies have experienced significant volatility. The trading performances of the securities of these companies at the time of or after their offerings may affect the overall investor sentiment towards China-based companies listed in Hong Kong and consequently may impact the [REDACTED] performance of our Shares. These broad market and industry factors may significantly affect the [REDACTED] and volatility of our Shares, regardless of our actual operating performance, and may result in losses on your [REDACTED] in our Shares.

In addition to market and industry factors, the price and [REDACTED] for our Shares maybe highly volatile for specific business reasons. In particular, factors such as variations in our revenue, earnings, and cash flow could cause the [REDACTED] of our Shares to change substantially. Any of these factors may result in large and sudden change in the volume and [REDACTED] price of our Shares.

The price of our Shares when [REDACTED] begins could be lower than the [REDACTED].

The Shares will not commence [REDACTED] on the Stock Exchange until they are delivered. Accordingly, holders of our Shares are subject to the risk that the price of the Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of [REDACTED] and the time [REDACTED] begins.

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

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

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

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 product candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] in our Shares as a source for any future dividend income. Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your [REDACTED] in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your [REDACTED] in our Shares and you may even lose your entire [REDACTED] in our Shares.

We are a Cayman Islands company and you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Memorandum and Articles of Association as well as the Cayman Companies Act and the common law of the Cayman Islands. The rights of shareholders are to a large extent governed by the common law of the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those in Hong Kong and other jurisdictions. See Appendix III in this document for further information.

There can be no assurance of the accuracy or completeness of certain facts, forecasts and other statistics obtained from various government publications and industry reports contained in this document.

This document, particularly the section headed “Industry Overview” contains information and statistics relating to the pharmaceutical industry. Certain information and statistics have been derived from various government publications, other third-party reports, either commissioned by us or publicly accessible, and other publicly available sources. The information and statistics from such sources have not been independently verified by us, the Joint Sponsors, the Overall Coordinators, [REDACTED], any of their respective directors, employees, agents or advisers or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate. Accordingly, You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

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

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