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## RISK FACTORS

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

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

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks relating to our business, business operations, intellectual property rights and financial prospects; (ii) other risks relating to our business, comprising (a) risks relating to the development of our drug candidates, (b) risks relating to extensive government regulation, (c) risks relating to manufacturing of our drug candidates and drugs, (d) risks relating to commercialization of our drugs, (e) risks relating to our intellectual property rights; and (f) risks relating to our reliance on third parties; (iii) other risks relating to our financial position and need for additional capital; (iv) other risks relating to our operations; (v) risks relating to our doing business in China; and (vi) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also harm our business, financial condition, results of operations and prospects. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

### **KEY RISKS RELATING TO OUR BUSINESS, BUSINESS OPERATIONS, INTELLECTUAL PROPERTY RIGHTS AND FINANCIAL PROSPECTS**

**We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.**

The development and commercialization of new drugs, especially biological products, is highly competitive. We face competition from other pharmaceutical companies and biopharmaceutical companies worldwide. There are a number of large pharmaceutical and biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of the same indications for which we are developing our drug candidates. Some of these competitors have better resources and expertise than us. In particular, we face intense competition in the development of CD47-targeting molecules. In recent years, the therapeutic potential of CD47-targeted agents in lymphoma, MDS/CMML and AML has been validated by accumulating clinical data. For example, in clinical trials, Gilead’s magrolimab in combination with azacitidine has delivered an ORR of 75% and 73% in the first-line treatment of MDS and AML, respectively. IMM01, our Core Product, is an innovative CD47-targeted molecule and is being developed for the treatment of various hematologic malignancies and solid tumors in combination with other agents. There are numerous drug developers of CD47-targeted molecules globally. For example, multiple companies, including large multi-national pharmaceutical companies, are also developing CD47-targeting therapies for hematologic malignancies and solid tumors, including ALX Oncology, Trillium Therapeutics/Pfizer, Forty Seven/Gilead, I-MAB and Innovent. For details, please refer to the paragraphs headed “Business — Our Innate Immune Checkpoint-targeted Drug Candidates — IMM01 (SIRP $\alpha$ -Fc Fusion Protein) — Our Core Product

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— Market Opportunities and Competition.” Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. In light of the intense competition within the market for CD47-targeted molecules, we may not be able to compete effectively and obtain substantial market share even if we successfully complete the development and commercialization of IMM01. We anticipate that we will face increasing competition as new drugs enter the market and advanced technologies become available.

Our commercial opportunity could be reduced or even eliminated if our competitors develop and commercialize drugs that are safer, have fewer or less severe side effects, or are more effective, convenient or less expensive than any drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, FDA, or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our drug candidates.

Mergers and acquisitions in the pharmaceutical and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative or licensing arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

**We depend substantially on the success of our clinical-stage and preclinical stage drug candidates. If we are unable to successfully complete development, obtain regulatory approval and commercialize our drug candidates, or if we experience significant delays in doing any of the foregoing, our business, financial condition, results of operations and prospects will be materially harmed.**

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

- successful completion of preclinical and clinical studies;
- obtaining positive results in our clinical trials demonstrating efficacy, safety and durability of effect of our drug candidates;
- receipt of regulatory approvals for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization;
- successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- sufficient resources to acquire or discover additional drug candidates;
- establishing sufficient commercial manufacturing capabilities, by expanding our existing facilities, building new facilities, and collaborating with CROs and CDMOs;

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- the performance by CROs, CDMOs 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;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties;
- successfully launching commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining favorable governmental and private reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug products; and
- continued acceptable safety profile of our drug candidates following regulatory approval.

As of the Latest Practicable Date, we had eight ongoing clinical programs in China and/or the U.S., five IND/IND-enabling-stage programs, and multiple discovery- and preclinical-stage assets. However, we cannot guarantee that we will be able to obtain regulatory approvals for our drug candidates in a timely manner, or at all. In addition, none of our drug candidates has been approved for marketing in any jurisdiction. Our pipeline products may require additional preclinical and/or clinical development, regulatory approvals, building of manufacturing capabilities and capacities, and substantial investment and significant marketing efforts, before we are able to generate any revenue from product sales.

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

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If the results of clinical trials of our product candidates are not positive or only modestly positive for proposed indications or if they raise safety concerns, we may (i) be subject to substantial liabilities, (ii) be delayed in or even prevented from obtaining regulatory approval for our drug candidates, (iii) obtain approval for indications that are not as broad as intended, (iv) have the product removed from the market after obtaining regulatory approval, (v) be subject to additional post-marketing testing requirements, (vi) be subject to restrictions on how the product is distributed or used; or (vii) be unable to obtain reimbursement for use of the product. Any of such events could materially and adversely affect our ability to commercialize the subject products and generate revenue.

A major risk we face is the possibility that we may be prevented or delayed in obtaining marketing approval for such product candidates if the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates. In some instances, there can be significant variability in safety or efficacy results between different preclinical studies and clinical trials of the same drug candidate due to numerous factors, including

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changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

While we are in early stages of clinical trials with our product candidates, it is likely that there may be side effects associated with their use. For example, CD47-targeted agents are shown to cause blood toxicity in clinical trials, such as anemia, thrombocytopenia and hemagglutination (clumping of red blood cells). If the results of our trials reveal a high and unacceptable severity and prevalence of these or other side effects associated with our drug candidates, our trials could be suspended or terminated and the NMPA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any or all targeted indications, and we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, the laws and regulations governing clinical trials are evolving rapidly, and the interpretations and enforcement of these laws and regulations may bring uncertainties to our drug development process. For example, the Center for Drug Evaluation recently released the Clinical Value-Oriented Anti-tumor Drug Clinical Research and Development Guideline, or the Guideline, which requires that clinical trials shall be designed in a more patient-friendly manner and shall consider the patients' actual needs when identifying drug candidates. The Guideline releases a signal from the PRC government to raise the quality and safety standards on clinical trials for oncology drugs. Such evolving rules may make it more difficult and costly for us and other biopharmaceutical companies to identify oncology drug candidates, obtain regulatory and ethic approvals, and enroll and maintain subjects for clinical trials.

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

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the NMPA, the FDA, or similar regulatory authorities, or if there are delays in the enrollment of eligible subjects as a result of the competitive clinical enrollment environment. Overall, we may experience difficulties in subject enrollment in our clinical trials for a variety of reasons, including but not limited to:

- severity of the disease under investigation;
- the size and nature of the subject population;
- the subject eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of subjects to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

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- clinicians' and subjects' perceptions of the potential advantages and side effects of the drug candidate under study compared to other available therapies;
- our ability to obtain and maintain subject consents;
- the risk that subjects enrolled in clinical trials will not complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

Our clinical trials may compete with clinical trials for other drug candidates that are in the same therapeutic areas as our drug candidates. This competition will potentially reduce the number and types of subjects available to us, since some subjects who might have opted to enroll in our trials may instead opt for a trial being conducted by our competitors. Even if we are able to enroll a sufficient number of subjects in our clinical trials, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and materially and adversely affect our ability to advance the development of our drug candidates.

**We have no track record with very limited experience in launching and marketing approved drugs, and we may not be able to successfully create or increase market awareness of our drugs or sell our products, which will materially affect our ability to generate sales revenue.**

Our financial performance depends on the successful launching and marketing of our clinical-stage and preclinical stage drug candidates. As all of our drug candidates are in the development stage, we have not yet demonstrated an ability to commercialize any of our drug candidates. Our ability to successfully commercialize approved drugs may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing approved drugs.

We will build up our commercialization and distribution capabilities to maximize our product offering and expedite market acceptance of our products. We will have to compete with other pharmaceutical and biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. There can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities to successfully commercialize any of our drug candidates, if and when approved, and as a result, we may not be able to generate sales revenue as planned.

If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities, we will likely pursue collaborative arrangements regarding the sales and marketing of our approved drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or that we will have effective sales forces after establishing such collaborative arrangements. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves in a cost-effective manner. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates. In case we cannot develop and successfully maintain in-house sales and commercial distribution capabilities or collaborate with third parties to successfully commercialize our products, we may not be able to generate product sales revenue and our business and prospects may suffer.

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**We have incurred significant net losses since inception. We expect that we will continue to incur net losses for the foreseeable future and we may not be able to generate sufficient revenue to achieve or maintain profitability. [REDACTED] are at risk of losing substantially all of their [REDACTED] in our H Shares.**

We have incurred losses in each period since our inception. In 2021, 2022 and the four months ended April 30, 2023, we had total comprehensive expenses of RMB732.9 million, RMB402.8 million and RMB111.8 million, respectively. Our total comprehensive expenses mainly resulted from research and development expenses, administrative expenses, as well as loss from changes in fair value of financial liabilities at FVTPL. We no longer recorded financial liabilities at FVTPL since January 31, 2022, as the investors’ preferred rights in connection with our series of financings, including liquidation preferences, redemption rights and anti-dilution rights, were terminated on the same day. We consider loss from changes in fair value of financial liabilities at FVTPL, together with share-based payments and [REDACTED] expenses, as non-cash expenses. Our adjusted net loss (non-IFRS measure) was RMB182.5 million, RMB225.8 million and RMB71.3 million in 2021, 2022 and the four months ended April 30, 2023, respectively. For more information about our net losses, see “Financial Information — Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income” in this document. We expect to continue to incur losses and expenses for the foreseeable future, primarily arising from the following events:

- conducting clinical trials of our drug candidates;
- engaging with CROs and CDMOs in and out of China;
- constructing our new GMP manufacturing facility;
- seeking regulatory approvals for our drug candidates;
- commercializing our drug candidates upon obtaining marketing approval, including establishing a sales, marketing and commercialization team for any future approved products;
- hiring additional clinical, quality control and R&D personnel;
- seeking to identify additional drug candidates;
- obtaining, maintaining, expanding and protecting our intellectual property portfolio; and
- enforcing and defending any intellectual property claims.

In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a development-stage or commercial-stage biopharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues, and the timing and amount of milestones and other payments we may receive through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our R&D efforts, expand our business, or continue our operations. A decline in the value of our Company may also cause you to lose substantially all or part of your [REDACTED].

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**Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain.**

Our commercial success depends in part on us and our collaborators avoiding infringement, misappropriation, and other violations of the patents and other intellectual property rights of third parties. We cannot guarantee that our drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, use or manufacture of the compounds we have developed or are developing. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future. Our Directors confirm that during the Track Record Period and up to the Latest Practicable Date, we were not involved in any legal, arbitral or administrative proceedings or disputes which allege that we were infringing, misappropriating or otherwise violating any intellectual property right of any third party.

We are aware of certain issued patents in the U.S. belonging to third parties that may potentially cover our CD47-based drug candidates and may not expire before our anticipated commercial launch of relevant drug candidates in the U.S. One of those patents was licensed to another drug developer of CD47-targeted molecules. While the clinical studies of our drug candidates are exempted from patent infringement under the U.S. patent laws, third parties who own those issued patents may initiate patent infringement claims or other legal proceedings against us to prevent us from commercializing our CD47-based products. Our Core Product IMM01 is one of the CD47-targeted drug candidates which may be subject to potential legal proceedings of patent infringement. As reviewed and advised by our legal advisor as to U.S. intellectual property law, Jun He Law Offices P.C.<sup>1</sup>, the scope of the relevant patent claims is too broad and the patent claims are obvious over prior art<sup>2</sup> or lack written description and enablement support<sup>3</sup>, the validity and enforceability of the third-party patents are thus questionable; as a result, if such third parties bring the legal proceedings against us, the risk that we will be determined by courts or other competent authorities in the U.S. to have infringed on such patent rights of the third parties is remote. The claims of a U.S. patent can be broad enough to generally cover the mechanism of

<sup>1</sup> A U.S.-based international law firm, Locke Lord LLP, was specifically engaged to analyze one certain relevant patent to assist our U.S. legal advisor to intellectual property laws, Jun He Law Offices P.C., in issuing its legal opinion.

<sup>2</sup> "Prior art" refers to publications or knowledge that are available to the public before the effective filing date of a patent application. Prior art may be used to evaluate whether a claimed invention in a patent application contains certain level of creativity (*i.e.*, more than just a simple and obvious improvement over what already exists). "Obvious over prior art" means that, though a claimed invention is different from the prior art, the difference can be readily conceived by a person having ordinary skills in the relevant field (*i.e.*, a hypothetical person who is familiar with the ordinary technical knowledge in that field) before the effective filing date of this claimed invention. Generally, a patent should involve inventive steps that are not obvious to a person having ordinary skills in such field. If the claimed invention is obvious over prior art, a patent for this claimed invention may not be obtained, and if obtained, it shall be invalid.

<sup>3</sup> "Lack of written description and enablement support" means the specification of a patent or patent application does not contain a written description of the invention which can enable any person having ordinary skills in the relevant field to make and use the same. Generally, a patent should have sufficient written description containing clear and detailed enough information and guidance so that a person having ordinary skills in that field would be readily able to practice the claimed invention. If the claimed invention lacks written description and enablement support, a patent for such a claimed invention may not be obtained, and if obtained, it shall be invalid.

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actions (MOA) of certain treatment methods for diseases. This means that a newly developed drug with a different structure or sequence could still be subject to potential risk of infringing the patent generally protecting the MOA of its target in the U.S. Our Core Product faces these risks due to the claims in the relevant U.S. patent which covers the use of polypeptides containing soluble human SIRP $\alpha$  to treat CD47+ cancers or tumors. Even using polypeptides with a different amino acid sequence could potentially result in patent infringement risks without obtaining a license from the patent owner. However, according to our legal advisors as to intellectual property law, the claims in the patent that may cover our CD47-based drug candidates are methods that had been disclosed in or suggested by certain prior patent applications and research publications (*i.e.*, prior art), rendering them “obvious over prior art” and lacking in patentability or validity. As of the Latest Practicable Date, neither we nor our legal advisors as to intellectual property law are aware of any patent infringement legal proceedings related to CD47-targeted drug candidates in China and globally.

However, whether a product infringes a patent 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 a third-party patent may be high. As such, even if we believe the claims are without merits, the outcome and impact of any potential legal proceedings initiated by third parties alleging that we may have infringed, misappropriated and/or otherwise violated their intellectual property rights would be dependent on court judgment and may not be in our favor. Parties making infringement or other intellectual property claims against us may obtain injunctive or other equitable relief, which could impact our ability to further develop and commercialize relevant product candidates. Such legal proceedings, regardless of their merits, could lead to considerable legal costs and be a distraction to our management.

If third parties, including the third parties that control the patents described above, eventually bring successful claims against us for infringement, misappropriation or other violations of their intellectual property rights, such claims could prevent us from commercializing one or more of our drug candidates. We may also have to pay substantial damages, including treble damages and attorneys’ fees under certain circumstances, or pay royalties and other related payments.

Alternatively, we may have to enter into royalty or licensing agreements with third parties in order to obtain the right to use their intellectual property rights, which agreements may not be available on terms acceptable to us, or at all. If we were unable to obtain such a license on reasonably acceptable terms, we might not be able to further develop and commercialize our drug candidates, which could harm our business significantly. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were able to ultimately prevail, or to settle at an early stage, such litigation could burden us with adverse impacts on our business and prospects.

**If we are unable to obtain and maintain adequate intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, our current or any future patents may be challenged and invalidated even after issuance.**

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technologies that we consider commercially important by filing patent applications in China, the U.S. and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. As of the Latest Practicable Date, we owned (i) nine



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issued patents in the PRC, (ii) eight issued patents in the U.S., (iii) eleven issued patents in other jurisdictions, and (iv) 31 patent applications, including two pending PRC patent applications and one PRC patent application filed as a priority application, one pending Hong Kong patent application, six pending U.S. patent applications, six PCT patent applications which have entered into national phases, five pending PCT patent applications which may enter various contracting states in the future, one PCT patent application filed as a priority application, and nine pending applications in other jurisdictions. Please refer to the paragraph headed “Statutory and General Information — Further Information about the Business of our Company — Our Material Intellectual Property Rights” in Appendix IV to this document for further information of our material intellectual property rights.

In 2019, we signed a technology transfer agreement with SunHo (China) Biopharmaceutical Co. Ltd (“SunHo”, a clinical-stage biotech company based in China), pursuant to which such third party acquired certain rights and interests (including one patent application in China relating to IMM2505) from us to develop and commercialize IMM2505 in China (including Hong Kong, Macau and Taiwan), while we retain the full rights and interests to IMM2505 in the rest of the world, and grant SunHo a single-digit percentage of interest in the overseas rights of IMM2505. IMM2505 is a CD47 and PD-L1 bispecific molecule internally discovered by us, which is different from IMM2520. We were the initial applicant of the patent application of IMM2505 in China, and pursuant to the technology transfer agreement, we have transferred the Chinese patent application regarding IMM2505 to such third-party transferee. The Chinese patent application of IMM2505 has been issued, and the issued claims of the Chinese patent are limited to specific amino acid sequences of an anti-PD-L1 antibody. These sequences differ from the amino acid sequences of the anti-PD-L1 antibody used in IMM2520, ensuring that IMM2505’s patent protection does not extend to cover IMM2520. As of the Latest Practicable Date, other than the above-mentioned patent of IMM2505 in China, for IMM2505, we owned one patent family, which includes one issued patent in the U.S. and one issued patent in Japan; for IMM2520, we owned one patent family, which includes one issued patent in Japan, one issued patent in the U.S., one issued patent in China, one pending patent application in the EU, and one pending PCT application which may enter various contracting states in the future. We own the full rights to develop and commercialize IMM2505 in jurisdictions other than China (including Hong Kong, Macau and Taiwan), and shall share with SunHo certain interests as agreed in the technology transfer agreement. In addition, we own the full rights to develop and commercialize IMM2520 in and outside of China.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. If we are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed. In addition, the requirements for patentability differ in certain jurisdictions. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Patent applications may not be granted and the granted patents may be invalidated for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our R&D output in time to obtain patent protection. Any of these reasons may delay or interfere with our commercialization plans in China and other overseas

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markets. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our R&D output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in China, the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. An adverse determination in any proceeding challenging our patent rights could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. In addition, the patent position of biopharmaceutical and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Furthermore, although various extensions may be available, the life of a patent and the protection it offers is limited. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Our issued patents for our drug candidates are expected to expire on various dates as described in “Business — Intellectual Property” of this document. Upon the expiration of these patents, we will not be able to assert such patent rights against potential competitors, and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Additionally, patent rights we own currently or in the future or may license in the future may be subject to a reservation of rights by one or more third parties.

**Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.**

To obtain regulatory approval for the sale of our drug candidates, we are required to conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical trials are expensive, difficult to design and implement, and can take years to complete,

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with uncertainty as to the outcomes. Our current drug candidates and any future drug candidates are susceptible to the risks of failure inherent at any stage of drug development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. While we believe some of our drug candidates have the potential to be innovative and differentiated globally, we cannot guarantee that we will be able to realize such potential for any of our drug candidates. Failure can occur at any time during the clinical development process.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through preclinical studies and initial clinical trials, and despite the level of scientific rigor in the design of such studies and trials and the adequacy of their execution. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, differences in individual patient conditions, including genetic differences, and other compounding factors, such as other medications or pre-existing medical conditions, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. Furthermore, as our drug candidates are developed through preclinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives.

Any disruptions, changes and delays in completing our clinical trials may increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate revenue for that drug candidate. Any of these occurrences may harm our business, financial condition and prospects significantly. We may adjust our clinical development strategy from time to time based on our evaluation of emerging data to maximize the value of our entire product portfolio. In light of the emerging data from our various clinical programs and prevailing industry trends, we terminated the Phase II trial of IMM01 monotherapy in October 2022, and strategically reallocated our resources to prioritize the development of combination and bispecific therapies in our pipeline. For details, see “Business — Our Innate Immune Checkpoint-targeted Drug Candidates — IMM01 (SIRP $\alpha$ -Fc Fusion Protein) — Our Core Product — Summary of Clinical Trial Results — IMM01 Monotherapy.” Although we believe that our strategically planned clinical development approach is designed to optimize the clinical and commercial potential of our drug candidates, we cannot guarantee that our specific plans will always efficiently anticipate regulatory and market trend shifts or be successfully implemented.

**We may face damage to, destruction of or interruption of production at our facilities, which could interrupt our development plans or commercialization efforts.**

The manufacturing of our drug candidates during the drug development stage relies on our own pilot production lines and the cooperation with CROs and CDMOs. Currently, we have built pilot production lines that can meet needs for the manufacturing of our IMM01 for use of clinical trials. Any interruption in manufacturing operations at our facilities could result in our inability to satisfy the demands of our clinical trials. A number of factors could cause interruptions, including equipment malfunctions or failures, technology malfunctions, outbreak of infectious diseases such as COVID-19, work stoppages, damage to or destruction of either facility due to natural disasters or other unanticipated catastrophic events.

If our manufacturing facilities, in particular our pilot production lines, are damaged or destroyed, we may not be able to replace our manufacturing capacity in a timely or cost-effective manner, or at all. In the event of a temporary or protracted loss of our pilot production lines or

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other production facilities or equipment, we might not be able to source manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements, and we would need regulatory agency approval before selling any drug products that are manufactured at that facility.

**We are constructing our GMP facilities for manufacturing. Any delays in completing and receiving regulatory approvals for our manufacturing facilities, or any disruption in the development of new facilities, could reduce or restrict our production capacity or our ability to develop or sell products, which could have a material and adverse effect on our business, financial condition and results of operations.**

In line with our future manufacturing and commercialization demands, we are currently building our own GMP manufacturing facility in Shanghai, China. We plan to complete the first stage of construction by 2025, which will provide us with an additional manufacturing capacity. We also plan to commence second stage of construction depending on the schedule of the regulatory approval and sales ramp-up of our drug portfolio in the future. However, the construction of such manufacturing facility may encounter delays or interruptions due to a number of factors, some of which are beyond our control. Such delays and interruptions could reduce or restrict our production capacity, slow down our drug development and commercialization efforts, especially if we could not source manufacturing to a third party in a timely or cost-effective manner. Even if collaboration with a third party is feasible, we will incur additional manufacturing costs. All could have a material and adverse effect on our business operations, financial condition and results of operations.

Cost overruns associated with constructing or maintaining our new facility could require us to raise additional funds from other sources. Our manufacturing facility is required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, FDA or other comparable regulatory authorities to ensure compliance with GMP regulations. Further, we will be subject to continued review and site inspections to assess compliance with GMP and adherence to commitments made in any biologics license application, other marketing application and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to spend time, money and efforts in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, to obtain FDA approval for our products in the U.S., we would need to undergo strict pre-approval inspections of our manufacturing facilities. Historically, manufacturing facilities in China have had difficulty meeting FDA standards. When inspecting our manufacturing facilities, the FDA may cite GMP deficiencies. Remediating deficiencies can be laborious, time consuming and costly. Moreover, the FDA will generally re-inspect the facility to determine whether the deficiency was remediated to its satisfaction and may note further deficiencies during re-inspection.

Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or their commercialization, if approved. Regulatory authority may also impose fines, injunctions, civil penalties, suspension or withdrawal of approvals, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so.

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**We had net cash outflows from our operating activities during the Track Record Period, and we may need to obtain additional financing to fund our operations. If we are unable to obtain sufficient financing on terms acceptable to us or at all, we may be unable to complete the development and commercialization of our drug candidates.**

We had net cash used in operating activities of RMB190.5 million, RMB238.7 million and RMB79.2 million in 2021, 2022 and the four months ended April 30, 2023, respectively. While we believe we have sufficient working capital to fund our current operations, we expect that we may experience net cash outflows from operating activities for the foreseeable future.

Our drug candidates require substantial investments for the completion of clinical development, regulatory review, drug manufacturing, marketing and launch before they can generate product sales revenue. Our operations have consumed substantial amounts of cash since our inception. We will need to expend substantial resources on the R&D and commercialization of our product pipelines. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials;
- the outcome, timing and costs of regulatory approvals of our drug candidates;
- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- the construction progress of our manufacturing facilities;
- our effective management of our CROs, CDMOs and other collaboration partners and associated costs;
- selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the cost of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights;
- the amount and timing of any profit sharing, milestone and royalty payments we receive from our future collaborators;
- cash requirements of any future development of other pipeline drug candidates;
- our headcount growth and associated costs; and
- the costs of operating as a public company and our need to implement additional internal systems and infrastructure, including but not limited to financial and reporting systems.

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We expect our cash operating costs will increase significantly in light of our expanding clinical trial programs. If the financial resources available to us are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

### **The COVID-19 pandemic could adversely impact our business, including our clinical trials.**

Since the end of December 2019, the outbreaks of a novel strain of coronavirus named COVID-19 have materially and adversely affected the global economy. Many countries and regions where we or our customers operate, including the PRC, the U.S., Europe and Japan, had been affected by the COVID-19 outbreaks and, in response, had imposed certain lockdown measures, closure of workplaces and restrictions on mobility and travel to contain the spread of the virus. The most recent one was the regional outbreak of COVID-19 variants in mainland China, and a series of control measures have been taken in an attempt to contain its spread in 2022. In late 2022, China began to modify its COVID-19 policy, and most of the travel restrictions and quarantine requirements had been lifted since then. However, if the pandemic gets worsen in the future due to reasons such as the emergence of a more severe variant of COVID-19 and the control measures that were once imposed reinitiate, we may experience one or more of the following disruptions to drug development efforts and business operations:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays or difficulties in dosing patients, or the risk that patients enrolled or dosed in clinical trials may drop out of the trials before completion;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in logistics that may affect the transport of clinical trial materials;
- interruption of key clinical trial activities, such as clinical trial site monitoring;
- changes in local regulations which may require us to change the ways in which our clinical trials are conducted;
- temporary closure of certain office facilities and adopting remote working where possible;
- restriction of employee travels, which may adversely affect the sales and marketing efforts;
- disruption to the manufacturing activities;
- disruption to the supplies of our drug candidates in clinical trials; and

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- delays in or temporary suspension of the construction of our new GMP manufacturing facility.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section. For details, see “Financial Information — Impact of the COVID-19 Outbreaks” in this document.

We cannot guarantee that the COVID-19 outbreak will not worsen. The extent to which the COVID-19 outbreak may impact our business in the future will depend on future developments, which are highly uncertain and unpredictable, such as the duration of the outbreak, the effectiveness of travel restrictions, the effectiveness of vaccines and vaccination rates in China and overseas, and other measures to contain the outbreak and its impact in China, the U.S., Europe, Japan and other countries where we and our customers operate. Having considered that the past occurrences of epidemics, depending on their scale, have caused different degrees of damage to the global and China’s economy, the COVID-19 outbreaks and any other public health crisis in China or overseas, especially in the cities where we have presence, may result in material disruptions to our operations, which in turn may materially and adversely affect our business, financial condition and results of operations.

### OTHER RISKS RELATING TO OUR BUSINESS

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

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

Although a substantial amount of our effort will focus on the continued clinical testing, potential regulatory approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to discover, develop, license, or commercialize additional drug candidates. However, we may not be successful in discovering and developing new drug candidates. Although we have developed technology platforms, such as the “mAb-Trap bispecific” technology platform which we believe enables us to design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in discovering and developing potential drug candidates. We may also pursue collaboration with third parties in the discovery and development of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results.

Research programs to discover and develop new drug candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or drug candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization for a number of reasons, including, without limitation, the following:

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

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Accordingly, there can be no assurance that we will be able to discover and develop new drug candidates or identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects.

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

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

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

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



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*We may seek approvals from the NMPA, FDA or other comparable regulatory authorities to use data from registrational trials via accelerated approval pathways for our drug candidates. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that we contemplate, which would increase the expense of obtaining, and delay the receipt of, necessary marketing approvals, if we receive them at all.*

The NMPA, FDA and comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial and grant accelerated approval to a drug candidate that provides meaningful therapeutic benefit over available therapies, for treatment of a serious or life-threatening condition. The determination is made based on a finding that the drug candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. For example, the FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity or mortality. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. Prior to seeking such accelerated approval, we will continue to seek feedback from the NMPA, FDA and otherwise evaluate our ability to seek and receive such accelerated approval.

There can be no assurance that in the future regulatory authorities will agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit any new drug applications, or NDAs, or other comparable applications, for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our drug candidates, would result in a longer time period for commercialization of such drug candidate, could increase the cost of development of such drug candidate, and could harm our competitive position in the marketplace. Even if we obtain accelerated approval of a drug candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the drug candidate and, if the post-approval trial is not successful, we may not be able to continue marketing the drug for the relevant indication. Pursuant to the PRC Drug Administration Law, the Administration Measures for Drug Registration, and the Working Procedures for the Review and Approval of Conditionally Approved Drugs (Trial), if (i) we fail to prove the benefits of a conditionally approved drug outweigh its risks through the post-approval research, or (ii) we fail to complete the required post-approval research within the prescribed time limit and submit the supplementary applications in order to obtain a full marketing approval, the NMPA will take actions in accordance with the relevant laws and regulations, including, in the worst case, the revocation of the drug registration certificate.

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

The global biologics market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. In 2021, 2022 and the four months ended April 30, 2023, our R&D expenses were RMB176.0 million, RMB277.3 million and RMB75.0 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that enable us to enhance the scope and quality of our clinical trials. 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, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

### **Risks Relating to Extensive Government Regulations**

*All material aspects of the research, development, manufacturing and commercialization of our drug candidates are heavily regulated and are subject to change. Any failure to comply with existing regulations and industry standards or any adverse actions by the 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 intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. We intend to initially focus our activities in China while pursuing overseas opportunities, particularly in the U.S. The pharmaceutical and biopharmaceutical industries in these jurisdictions are subject to comprehensive government regulation and supervision, in particular, regulation of the development, approval, manufacturing, marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in each of these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislations may increase the difficulty and cost for us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects. In addition, we are subject to scheduled or unscheduled periodic inspections of our facilities to monitor our regulatory compliance. During the Track Record Period, we passed all the inspections and obtained clearance in relation to discovery and development of our drug candidates from the regulatory authorities in all material respects. However, we cannot assure you that we will be able to do so going forward.

Failure to comply with the applicable regulatory requirements in the jurisdictions we operate or target to operate in the future at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include, but are not limited to, a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product

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recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our business, financial condition, results of operations and prospects.

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

Significant time, efforts and expenses are required to bring our drug candidates to market in compliance with the regulatory process, and we cannot assure you that any of our drug candidates will be approved for sale. The time required to obtain approvals from the NMPA, the FDA and other comparable regulatory authorities is often unpredictable, and depends on numerous factors, including the substantial discretion of the regulatory authorities. Our drug candidates could fail to receive regulatory approval in a timely manner for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or, it is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

In addition, the NMPA, the FDA or a comparable regulatory authority may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA and other comparable regulatory authorities may also change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may not obtain the regulatory approvals or may lose the approvals that we may have obtained and we may not achieve or sustain profitability.

Additionally, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative

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review periods. Seeking regulatory approvals in various jurisdictions could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our drug candidates will be approved for sale in those jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be compromised. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

***While we believe that our drug candidates' Category 1 designation in China should confer certain regulatory advantages on us, these advantages may not result in commercial benefits to us as we have expected, and may change in the future in a manner adverse to us.***

In China, prior to seeking approval from the NMPA, a pharmaceutical company needs to determine the drug's registration category, which will determine the requirements for its clinical trial and marketing application. The categories of therapeutic biologics range from Category 1 (new biologics: biologics that have not previously been marketed anywhere in the world), to Category 2 (improved biologics: biologics that have been previously marketed in China or abroad with improved safety, efficacy and quality control and that have obvious therapeutic advantages), to Categories 3 (biologics that have been previously marketed in China and abroad). Among our pipeline of drug candidates, all of our clinical-stage drug candidates are designated as Category 1 drug candidates.

The NMPA has adopted several mechanisms for expedited review and approval for drug candidates that apply to Category 1 drug candidates. While we believe that our clinical stage drug candidates that have been designated as Category 1 drugs should provide us with a significant regulatory, and therefore commercial advantage over non-Chinese companies seeking to market products in China, we cannot be sure that this will be the case. The pharmaceutical regulatory environment is evolving quickly, and changes in laws, regulations, enforcement and internal policies could result in the "favored" status of Category 1 products changing or being eliminated altogether or our products classification in Category 1 changing. We cannot be certain that the advantages we believe will be conferred by our Category 1 classifications will be realized or result in any material development or commercial advantage.

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

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. We receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state

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(the U.S.), national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. As of the Latest Practicable Date, we are primarily subject to numerous PRC laws, Hong Kong laws and U.S. federal and state laws governing data protection and privacy.

In recent years, the PRC authorities have promulgated certain laws and regulations in respect of information security, data collection and privacy protection regulations in the PRC, including the Cybersecurity Law of the PRC (中華人民共和國網絡安全法), the Provisions on Protection of Personal Information of Telecommunication and Internet Users (電信和互聯網用戶個人信息保護規定), the Cybersecurity Review Measures (網絡安全審查辦法), the Data Security Law of the PRC (中華人民共和國數據安全法) which became effective from September 1, 2021, the Personal Information Protection Law of the PRC (中華人民共和國個人信息保護法) which became effective from November 1, 2021, and the Measures for the Security Assessment of Outbound Data Transfer (數據出境安全評估辦法) which became effective from September 1, 2022. Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual prior consent shall be obtained, unless the Law indicates otherwise. Further, any data processing activities, that are in relation to the sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old, are not allowed, unless such activities have a specific purpose, are highly necessary and strictly protective measures have been taken.

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 (中華人民共和國人類遺傳資源管理條例), or the HGR Regulation, was promulgated by the State Council in May 2019 and came into effect in July 2019. 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 requirements under the HGR Regulation and other applicable laws, 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 (中華人民共和國生物安全法) 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. 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. For more information regarding the PRC laws and regulations governing data protection and privacy, see “Regulatory Overview — Overviews of Laws and Regulations in the PRC” in this document.

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

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limit the use and disclosure of individually identifiable health information, known as “protected health information,” and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations may require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. For more information regarding the US laws and regulations governing data protection and privacy, see “Regulatory Overview — Laws and Regulations in the United States” in this document.

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

In addition, our clinical trials frequently also involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs, CDMOs and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

***If we participate in compassionate use programs, current regulatory discrepancies among competent authorities of different countries may lead to increased risk of adverse drug reactions and serious adverse events arising from the use of our products.***

Compassionate use programs are regulatory programs that facilitate access to investigational drugs for the treatment of patients with serious or immediately life-threatening diseases or conditions that lack therapeutic alternatives. Currently, there is no unified approach or standard practice to regulate compassionate use programs among competent authorities in different

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countries for access to investigational drugs. In China, currently there is no officially approved regulation to oversee compassionate use programs. In the U.S., compassionate use programs are limited to patients who have a life-threatening disease or serious disease or condition, who may gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

The regulatory discrepancy for compassionate use programs among competent authorities in different countries may lead to uneven patient entry criteria and protocols for compassionate use programs. This may create increased risk of serious adverse events because of enrolled patients' advanced disease or comorbidities. In addition, because the products in compassionate use programs are investigational drugs, many of which are still in experimental stages and have not received marketing approval, patients in compassionate use programs may exhibit adverse drug reactions from using these products. If we participate in compassionate use programs, we may be subject to the risk of enrolled patients exhibiting adverse drug reactions or serious adverse events arising from the use of our products. These occurrences can potentially lead to clinical holds of our ongoing clinical trials or complicate the determination of the safety profile of a drug candidate under regulatory review for commercial marketing.

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

If any of our drug candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-market information, including requirements of regulatory authorities in China, the U.S. and other jurisdictions. These requirements also include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacture Practices, or the cGMP, and Good Clinical Practice, or the GCP, for any clinical trials that we conduct post-approval.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidates. The NMPA, FDA or a comparable regulatory authority may also require a REMS program as a condition of approval of our drug candidates or following approval.

Once a drug is approved by the NMPA, FDA or a comparable regulatory authority for marketing, 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. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the NMPA, FDA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;

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- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

In addition, we are subject to ongoing regulatory requirements for our day-to-day business operations. Accordingly, we and third parties we work with must continue to expand time, money and efforts in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China, the U.S. or other jurisdictions, where the regulatory environment is constantly evolving. If we are unable to maintain regulatory compliance, or if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may lose any regulatory approval that we have obtained, and we may not achieve or sustain profitability.

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

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction. We intend to seek approval to market our drug candidates in China, the U.S. and in other jurisdictions. In China and some markets outside China, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Thus, our ability to commercialize any approved drug candidates successfully will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In China, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security, together with other government authorities, regularly review the inclusion or removal of drugs from China’s National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (國家基本醫療保險、工傷保險和生育保險藥品目錄), or the NRDL. The NRDL determines a pharmaceutical product’s reimbursable amounts for program participants under the National Medical Insurance Program, or the NMIP. Under the NMIP, patients are entitled to full or partial reimbursement of costs for pharmaceutical products listed in the NRDL. A pharmaceutical product’s inclusion in or exclusion from the NRDL will significantly affect the demand for such product in China. There is no assurance that any of our future approved drug candidates will be included in the NRDL. The inclusion of pharmaceutical products by relevant authorities into the NRDL is based on a variety of factors, including efficacy, safety and price. The products included in the NRDL are typically generic and essential drugs, while innovative drugs similar to our drug candidates have historically been more limited on their inclusion therein due to the affordability of the government’s Basic Medical Insurance Program. In addition, the PRC government has implemented significant reforms of the pharmaceutical industry in recent years and may enforce additional measures in the future, which may adversely affect our pricing strategy for our pharmaceutical products.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require



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co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drug candidates. Patients are unlikely to use any of our future approved drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs. Because some of our drug candidates may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the coverage and reimbursement rates may be inadequate for us to achieve profitability.

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 drug candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidates that we commercialize. Obtaining or maintaining reimbursement for our future approved drug candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug 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.

***We may be directly or indirectly subject to 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 other jurisdictions, which could, in the event of noncompliance, expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell, and distribute our drug candidates, if approved. Such laws include the PRC Anti-Unfair Competition Law (中華人民共和國反不正當競爭法), the PRC Criminal Law (中華人民共和國刑法), the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, HIPAA, and the U.S. Physician Payments Sunshine Act.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Government authorities could conclude that our business practices may not comply with current or future 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

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penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, 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. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business. Furthermore, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***If safety, efficacy, manufacturing or supply issues arise with any drug product used in combination with or to facilitate the use of our drug candidates, we may be unable to market such drug candidates or may experience significant regulatory delays or supply shortages.***

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. For example, we are developing IMM01 in combination with other cancer agents, including azacitidine, tislelizumab, inetetamab, and bortezomib/dexamethasonum for a broad range of hematological cancers and solid tumors. If the NMPA, FDA or another comparable regulatory agency revokes or denies its approval of a component therapeutic, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts.

We do not manufacture or sell any component drugs we use in combination with our drug candidates. Instead, we primarily purchase the component drugs (such as tislelizumab and azacitidine) on the market with our own funds. Generally, we do not enter into collaboration agreements on the supply of certain drugs we use in our combination trials, such as azacitidine and tislelizumab, to avoid time-consuming negotiation and potential restrictions under the collaboration, thus ensuring our full control over the clinical development process and intellectual property rights. However, the absence of collaboration arrangements with drug suppliers may subject us to unstable supply. If we cannot purchase a sufficient amount of those component drugs from their manufacturers or distributors, or we experience any supply shortage of such component drugs, the clinical development of our drug candidates may be disrupted. The supply shortage may also delay the regulatory approval of our drug candidates or our ability to timely meet market demand for our products upon receipt of marketing approval, which will adversely affect our business and prospects.

Although we have not used companion diagnostic tests in the development of our drug candidates, it is common practice in the industry to use companion diagnostic tests to detect a predictive biomarker, such as PD-L1, EGFR and HER2, in patients to evaluate their likely response to certain treatment. In the U.S., the FDA has generally required in vitro companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. The regulations in China on the companion diagnostic test used for patient identification are still developing and require detailed interpretation and implementation. It remains uncertain whether the future regulatory changes would provide additional restrictions or requirements. If we determine to develop companion diagnostic tests in the future for patient screening or our drug development entails the use of such tests, the developing regulations in China would present uncertainties to our drug development and commercialization and may have an adverse effect on our business and results of operations.

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*Negative results from off-label use of our future marketed drug products could materially harm our business reputation, product brand and financial condition and expose us to liability.*

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions or adverse events. Any of these occurrences can create negative publicity and materially and adversely affect our business reputation, product brand, commercial operations and financial condition, including our share price. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our drug candidates.

### **Risks Relating to Manufacturing of Our Drug Candidates and Drugs**

*We have limited experience in manufacturing therapeutic biologic products on a large commercial scale, which is a highly exacting and complex process, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.*

We have limited experience in large-scale manufacturing of our products for commercial use. Moreover, the manufacturing of therapeutic biologics is highly complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities or the expansion of our existing manufacturing facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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

We may encounter problems with achieving adequate or clinical-grade products that meet the NMPA, FDA or other comparable regulatory agency standards or specifications, maintaining consistent and acceptable production costs. We may also experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities.

In addition, the quality of our products, including drug candidates manufactured by us for R&D purposes and, in the future, drugs manufactured by us for commercial use, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, jeopardize any GMP certifications we may have and harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

***If we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business could suffer.***

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand of our drug candidates, if approved, we will need to increase, or scale up, the production process by a significant factor over the initial level of production. If the scale up is delayed, the cost of this scale up is not economically feasible for us, or we cannot find a third-party supplier, we may not be able to produce our approved drug candidates in a sufficient quantity to meet future demand.

In anticipation of commercialization of our drug candidates, we aim to significantly expand our manufacturing capacity, mainly through the construction of our new manufacturing facility. However, the timing and success of the plan are subject to significant uncertainty. Moreover, such plan is capital intensive and requires significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all.

Furthermore, given the size of our new facility, we may not be able to fully utilize it immediately or within a reasonable period of time after we commence the operation. During the construction and ramp up period, there may be significant changes in the macroeconomics of the

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pharmaceutical and biopharmaceutical industry, including, among other things, market demand, product and supply pricing trends and customer preferences. Any adverse trends in these respects could result in operational inefficiency and unused capacity in our facility. We may also experience various unfavorable events in the course of developing our new manufacturing facility, such as:

- unforeseen delays due to construction, land use rights or regulatory issues, which could result in loss of business opportunities;
- construction cost overruns, which may require diverting resources and management's attention from other projects; and
- difficulty in finding sufficient numbers of trained and qualified staff.

The success of our business expansion also depends on our ability to advance drug candidates through the development, regulatory approval and commercialization stages. Any delay, suspension or termination in such respects would harm our ability to generate satisfactory returns on our investment in manufacturing expansion, if at all, which in turn could have a material adverse effect on our business, financial condition and results of operations.

### **Risks Relating to Commercialization of Our Drugs**

*Our drug candidates, once approved, may fail to achieve the degree of market acceptance by oncology physicians, hospitals, patients, third-party payers and others in the medical community that would be necessary for their commercial success, and the actual market size of our drug candidates might be smaller than expected.*

Even if our drug candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians and patients and others in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenue and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, medical treatment centers and patients considering our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labelling or package insert requirements of regulatory authorities;
- limitations or warnings contained in the labelling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage and reimbursement under the national and provincial reimbursement drug lists in the PRC, or from third-party payers and government authorities in other jurisdictions;

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- price control or downward adjustment by the government authorities or other pricing pressure, including the price reduction during the negotiation for inclusion in the national reimbursement drug lists;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

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

***If the market opportunities for our drug candidates are limited to those patients who are ineligible for or have failed prior treatments, the market could be small.***

We conduct our preclinical studies and clinical trials, based on our estimation of the number of patients who have the cancers we are targeting, as well as the subset of patients with these cancers who are able to receive different lines of therapies and who have the potential to benefit from the treatment with our drug candidates. New studies may change the estimated incidence or prevalence of these cancers. The number of eligible patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our drug candidates may be limited or may not be amenable to treatment with our drug candidates. Our business may suffer if the market opportunities for our product candidates are smaller than we anticipate, or the regulatory approvals we obtain for our drugs are based on a narrower definition of the patient population.

Given the small number of patients who have the eligibility criteria and diseases that we are targeting, it is critical to our profitability that we successfully identify such patients. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. New patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations and prospects.

### **Risks Relating to Our Intellectual Property Rights**

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

Competitors or other third parties may challenge the validity and enforceability of our patents, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant

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expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any such litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. Moreover, we may not be able to detect infringement against our patents. Even if we detect infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defense available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defense may make it impossible for us to enforce our patents against such third party.

In addition, although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaboration partners or other third parties have an interest in our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For instance, we may have inventorship disputes arising from conflicting obligations of employees, collaboration partners, consultants or others who are involved in developing our drug candidates or technologies. Litigation may be necessary to defend against these and other claims challenging inventorship of our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail to defend any claim, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could lead to substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***Issued patents covering one or more of our drug candidates could be found invalid or unenforceable if challenged in court.***

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, CNIPA or the applicable foreign counterpart, or made a misleading statement, during prosecution. Even if we conduct our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable.

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If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a drug candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activities and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, USPTO and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and other similar 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.

***Changes in patent and other intellectual property laws of China, the U.S. or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and future drugs.***

Our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

In China, the recent amendment to the PRC Patent Law, amended in October 2020 and implemented in June 2021, introduced patent term compensation mechanism for eligible invention patents related to new drugs. The patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products (if approved) without facing infringement risks. According to the PRC Patent Law, in order to compensate for the time used for the review and approval of new drugs for marketing, the patent administration department of the State Council shall, at the request of the patentee, provide patent term compensation for invention patents of new drugs approved for marketing in China. The patent term compensation may not exceed five years, and the total effective term of the patent after the new drug approved for marketing shall not exceed 14 years. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which



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may in turn render our products non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Under the America Invents Act, the AIA, enacted in 2011, the U.S. moved to first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literatures often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them.

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. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach 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 drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

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

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against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

While we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. 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. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

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

We currently own issued trademark registrations and have trademark applications pending, any of which 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. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the CNIPA, USPTO or comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

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Our 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.

### **Risks Relating to Our Reliance on Third Parties**

*We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.*

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

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

Our future revenue is dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake R&D programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to

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assist with our commercialization efforts. We do not have control over our collaborators, other than pursuant to our agreement with them. Therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators, and if any of our collaborators breaches or terminates their agreements with us, we may not be able to successfully commercialize the licensed product which could materially and adversely affect our business, financial condition, cash flows and results of operations.

*We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our collaboration partners.*

The development and potential commercialization of our drug candidates will require substantial additional capital to fund expenses. Historically we have entered into collaboration arrangements with third parties in relation to the development of our drug candidates. Please refer to the paragraphs headed "Business — Collaboration Agreements" in this document for further information on those collaboration arrangements. We may form or seek additional strategic partnerships, enter into licensing arrangements or establish other collaborative relationships with third parties that we believe will complement or augment our R&D and commercialization efforts with respect to our drug candidates. Any of these relationships may require us to incur additional expenses and charges, increase our near and long-term expenditures, issue securities that dilute the value of our shares, or disrupt our management and business. These transactions can also entail numerous operational and financial risks, including exposure to unknown liabilities, and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, drug candidates or technologies. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

Furthermore, we face significant competition in seeking appropriate strategic partners with whom we collaborate to develop our drug candidates, and the negotiation process is time-consuming and complex. We may not be always successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because, among other reasons, they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy.

If and when we collaborate with a third party for the development and commercialization of a drug candidate, we may also relinquish some or all of the control over the future success of that drug candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, drug candidates and market opportunities. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

Collaborations involving our drug candidates are subject to specific risks, which include, but are not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

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- collaborators may not pursue the development and commercialization of our drug candidates or may elect to cease collaboration due to change in their strategic focus, potential acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may not always be cooperative or responsive in providing their services in a clinical trial;
- disputes may arise between us and a collaborator that cause a delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborators may own or co-own intellectual property covering our drug candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right over such intellectual property.

As a result, we cannot be certain that, following a strategic transaction or license, we will be able to achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its 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 or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. Either would harm our business, financial condition, results of operations and prospects.

***We have a limited number of suppliers during the Track Record Period and the loss of one or more key suppliers could disrupt our operations.***

In each period of the Track Record Period, the aggregate purchases attributable to our five largest suppliers amounted to RMB55.9 million, RMB58.1 million and RMB14.7 million, respectively, representing 32.4%, 30.2% and 40.7% of our total purchases, respectively. During the Track Record Period, we had a number of suppliers, and the largest purchase amounts related to manufacturing and CRO services. Our other major purchases were fees paid to research and development services, equipment and construction works. We expect to continue our purchases from these suppliers as we fund the continuing R&D activities of our drug candidates in our pipeline. We believe that we have long and stable relationships with our existing large third-party suppliers. However, the stability of operations and business strategies of our suppliers are beyond our control, and we cannot assure you that we will be able to secure a stable relationship and high-quality outsourced services with our large suppliers. If any of our large suppliers terminates

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its business relationship with us, we may encounter difficulty in finding a replacement that can provide services of equal quality at a similar price. If this occurs, our operations may be significantly disrupted.

***If our third-party manufacturers fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices, our business could be harmed.***

In addition to our pilot product lines, we currently also engage third parties for the manufacturing of certain drug candidates for preclinical studies and clinical use. Such reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, FDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and GMP-compliance inspections by the NMPA, FDA or other comparable regulatory authorities;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic inspection, announced and unannounced, by the regulatory authorities to ensure strict compliance with GMP and other government regulations, and we do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers may be subject to inclement weather, as well as natural or human-made disasters.

Each of these risks could delay or suspend R&D activities, result in higher costs, or adversely impact commercialization of our future approved drug candidates. In addition, we will rely on third parties to perform certain specification tests, including abnormal toxicity tests, on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm, and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

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Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced regulations. Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any future approved drug candidates for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

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

Our business operations require a substantial amount of raw materials, such as active pharmaceutical ingredients, reagents and consumables, as well as equipment and other materials needed for R&D as well as manufacturing purposes. Currently, the materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the R&D of our drug candidates.

Moreover, we require a stable supply of materials for our drug candidates in the course of our R&D activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of marketing approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approval of our drug candidates or our ability to timely meet market demand for our commercialized products. Our suppliers may not be able to cater to our growing demand or may reduce or cease their supply of materials to us at any time. Even if our suppliers have adequate capacity to meet our demand, they may fail to deliver the materials to us in a timely manner due to logistics difficulties or other reasons beyond their control.

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

In addition, we cannot assure you that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our products. The non-compliance

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of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material and adverse effect on our business, financial condition and results of operation.

***Our Directors, employees, principal investigators, consultants, commercial partners and independent contractors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading, which could harm our reputation and subject us to penalties and significant expenses that have a material and adverse effect on our business, financial condition and results of operations.***

We are exposed to risks of fraud, bribery, misconduct or other illegal activity by our Directors, employees, principal investigators, consultants, commercial partners and independent contractors that could subject us to financial losses and sanctions imposed by government authorities, which may adversely affect our reputation. Misconduct by these parties could include, but not limited to, intentional, reckless and negligent conduct that fails to:

- comply with the laws of the NMPA, the FDA and other comparable regulatory authorities;
- provide true, complete and accurate information to the NMPA, the FDA and other comparable regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in China, the U.S. and similar fraudulent misconduct laws applicable to us; or
- report financial information or data accurately or disclose unauthorized activities to us.

If we obtain approval for any of our drug candidates and begin commercializing those drugs in China, the U.S., or other applicable jurisdictions, our potential exposure under relevant laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators of our clinical trials, and our use of information obtained in the course of patient recruitment for clinical trials, as well as proposed and future sales and marketing programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

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

During the Track Record Period, we were not aware of any instances of fraud, bribery, or other misconduct involving our Directors, employees and other third parties that had any material and adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies



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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.

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

#### **Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.**

The RMB has fluctuated against Hong Kong dollar and the U.S. dollar at times significantly and unpredictably. We incurred net foreign exchange losses of RMB9.1 million in 2021, net foreign exchange gains of RMB26.1 million in 2022, and net foreign exchange losses of RMB1.0 million in the four months ended April 30, 2023. We cannot assure you that RMB will not appreciate or depreciate significantly in value against Hong Kong dollar or the U.S. dollar in the future. It is difficult to predict how market forces may impact the exchange rate between RMB and foreign currencies in the future.

Significant revaluation of RMB may have a material and adverse effect on your [REDACTED]. For example, to the extent that we need to convert Hong Kong dollars we receive from this [REDACTED] into RMB for our operations, appreciation of RMB against Hong Kong dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert our RMB into Hong Kong dollars for the purpose of making payments for dividends on our H Shares or for other business purposes, appreciation of Hong Kong dollar against RMB would have a negative effect on the Hong Kong dollar amount available to us.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited, and we may not be able to adequately hedge our exposure or at all. As a result, fluctuations in exchange rates may have a material adverse effect on your [REDACTED].

#### **We have historically received government grants, subsidies and other preferential policies for our R&D and financing activities and enjoyed preferential tax treatment during the Track Record Period. Expiration of, or changes to, these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.**

We have historically benefited from government grants, subsidies and other preferential policies as incentives for our R&D and financing activities. We recognized RMB8.7 million, RMB5.2 million and RMB0.1 million in government grants in 2021, 2022 and the four months ended April 30, 2023, respectively. We have been accredited as a High and New Technology Enterprise under the relevant PRC laws and regulations and enjoy a preferential tax rate of 15% for a term of three years starting from 2020. Although we expect to continuously benefit from government grants and preferential tax treatment, the local government authorities have the sole discretion to determine the timing, amount and criteria of such financial incentives. We generally do not have the ability to influence local government authorities in making these decisions. Local authorities may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, otherwise we may be deprived of all or part of the incentives, which may have an adverse effect on our business, financial performance and results of operations.

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**We had net liabilities and net current liabilities as of December 31, 2021. We cannot assure you that we will not experience net liabilities and/or net current liabilities in the future, which could expose us to liquidity risks.**

We had net liabilities of RMB1,598.4 million as of December 31, 2021, and we recorded net current liabilities of RMB1,773.7 million as of December 31, 2021. Our financial liabilities at FVTPL, which primarily accounted for our net current liabilities and net liabilities, were RMB2,431.6 million as of December 31, 2021. Our financial liabilities at FVTPL consisted of financial instruments related to the equity interests with preferred rights held by our investors. We no longer recorded any financial liabilities at FVTPL since January 31, 2022, as the investors’ preferred rights in connection with our series of financings, including liquidation preferences, redemption rights and anti-dilution rights, were terminated on the same day. As a result, we recorded net assets of RMB779.2 million and RMB697.6 million as of December 31, 2022 and April 30, 2023, respectively, and net current assets of RMB600.1 million and RMB521.8 million as of December 31, 2022 and April 30, 2023, respectively. While we believe we have sufficient working capital to fund our current operations, we may have net liabilities and/or net current liabilities for the foreseeable future. Net liabilities and/or net current liabilities position can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. If we are unable maintain adequate working capital or obtain sufficient equity or debt financings to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

***Our financial performance and results of operations may be adversely affected by fair value changes and credit risk associated with our financial assets at FVTPL.***

We made investment in certain wealth management products and structured deposits during the Track Record Period, and our investment was limited to principal-guaranteed and low-risk products from reputable financial institutions. As of December 31, 2021, December 31, 2022 and April 30, 2023, we recorded financial assets at FVTPL of nil, nil and RMB25.0 million, respectively. For details about our financial assets at FVTPL, see note 24 to the Accountants’ Report set out in the Appendix IA to this document. Our financial assets at FVTPL are stated at fair value, and net changes in their fair value are recorded as other gains and losses, and therefore directly affect our results of operations. We may in the future make investment in certain wealth management products and structured deposits that provide better investment returns than term deposits at commercial banks. We cannot assure you that market conditions and regulatory environment will create fair value gains or we will not incur any fair value losses on our financial assets at FVTPL in the future. If we incur such fair value losses, our financial performance and results of operations may be adversely affected.

***Share-based payments may impact our financial performance and cause shareholding dilution to our existing Shareholders.***

We adopted the restrict share scheme and granted restricted shares to certain employees, directors and consultants to incentivize and reward the eligible persons who had contributed and would continue to contribute to the success of our Company. In 2021, 2022 and the four months ended April 30, 2023, we recorded non-cash share-based payments of RMB34.0 million, RMB103.8 million and RMB30.1 million, respectively. To further incentivize our employees, directors and consultants and align their interests with ours, we may grant additional share-based compensation in the future. Expenses incurred with respect to such share-based payment may increase our operating expenses and therefore have an adverse effect on our financial performance. Issuance of additional Shares with respect to such share-based payment may also dilute the shareholding percentage of our existing Shareholders.

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## RISK FACTORS

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*The impairment of our prepayments and other receivables may affect our business operations.*

Our prepayments and other receivables were RMB27.5 million, RMB16.6 million and RMB16.5 million as of December 31, 2021, December 31, 2022 and April 30, 2023, respectively. Our prepayments and other receivables consisted of prepayments for research and development related services and materials, and other receivables. For details, see note 21 to the Accountants’ Report set out in Appendix IA to this document. We conduct assessments on the recoverability of prepayments and other receivables based on, among others, our historical settlement records, our relationship with relevant counterparties, payment terms, current economic trends and to a certain extent, the larger economic and regulatory environment, which involve the use of various judgments, assumptions and estimates by our management. However, there is no assurance that our expectations or estimates will be entirely accurate, or any precautions we take to prevent an impairment will be effective, as we are not in control of all the underlying factors affecting such prepayments and other receivables. If we are not able to recover the prepayments and other receivables as scheduled, our financial position and results of operations may be adversely affected.

### OTHER RISKS RELATING TO OUR 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 delay or prevent the successful development of our drug candidates and result to a material and adverse effect on our business and results of operations.**

Our commercial success depends significantly on the continued service of our senior management. For more details of our senior management, see the paragraphs headed “Directors, Supervisors and Senior Management” in the Document. The loss of any of our senior management could have a material adverse effect on our business and operations. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time.

Recruiting and retaining qualified scientific, technical, clinical, sales and marketing personnel in the future will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategy. To retain valuable employees, in addition to salary and cash incentives, we have provided share incentives that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the market price of our H Shares that are beyond our control and may, at any time, be insufficient to counteract more lucrative offers from other companies. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the pharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced senior management or key 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 and adverse effect on our business and results of operations

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## RISK FACTORS

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Furthermore, replacing executive officers, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biopharmaceutical companies for similar personnel. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

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

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. Litigation to which we subsequently become a party might result in substantial costs and divert management's attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings that may initially not appear to be of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Additionally, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material and adverse effect on our financial condition, results of operations or reputation.

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

We are subject to anti-bribery laws in China 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. In addition, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act, the FCPA. The FCPA 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, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

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## RISK FACTORS

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

As we operate in the PRC, the U.S. and conduct our clinical trials in these jurisdictions, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- differences between national and local practice with respect to laws and regulatory requirements in a specific jurisdiction;
- difficulty of effective enforcement of contractual provisions in certain jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- inadequate intellectual property protection in certain jurisdictions;
- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- enforcement of anti-corruption and anti-bribery laws;
- trade protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, and greater difficulty in accounts receivable collection;
- compliance with tax, employment, immigration and labor;
- the effects of applicable local tax regimes and potentially adverse tax consequences;
- significant adverse changes in local currency exchange rates; and
- business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics, including, for example, the outbreak of COVID-19.

The occurrence of any one or more of these risks of doing business internationally, alone or in the aggregate, could materially adversely affect our business and results of operations.

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## RISK FACTORS

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

We face an inherent risk of product and professional liability as a result of the clinical testing and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulatory authorities;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any approved drug candidate; and
- a decline in the market price of our H Shares.

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

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## RISK FACTORS

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**Our internal 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.**

Our internal computer systems and those of our current and any future third-party vendors, collaborators, consultants, and third parties performing services for us, as well as our clinical sites and regulatory authorities, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures. In addition, the COVID-19 pandemic has intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely.

Although we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our drug candidate development and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from our current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in the theft or destruction of intellectual property, data, or other misappropriation of assets, financial loss, or otherwise compromise our confidential or proprietary information and disrupt our operations, our competitive position could be harmed, and the further development and commercialization of our drug candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of our company, our third-party vendors, and clinical sites, including personal information of our employees and, potentially, our clinical study patients, and company and vendor confidential data. In addition, third parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to data and systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, we could be subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls, and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated.

Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with clinical sites and collaborators, and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems, or those of third parties with which we conduct business, will be sufficient to protect us against breakdowns, service disruption, data deterioration, or loss in

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## RISK FACTORS

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the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks, or insider threat attacks, which could result in financial, legal, business, or reputational harm.

**If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud, and our business, financial condition, results of operations and reputation could be materially and adversely affected.**

Prior to this [REDACTED], we were a private company with limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting. In preparation for the [REDACTED], we engaged an internal control consultant to perform the internal control review, and the review scope covers certain areas including financial closing and reporting. We are in the process of implementing a number of measures to manage our risk exposure. However, we may not effectively monitor risks due to limited information resources or tools and other reasons. In addition, we cannot assure you that all of our employees will comply with our internal control systems and procedures. Although we regularly update our risk management systems and procedures, we may fail to predict risks arising from rapid changes in market conditions, regulatory measures and our entry into new markets. If we fail to effectively improve our risk management and internal control procedures and systems, or if we cannot achieve the intended results of such procedures or systems in a timely manner, our business, financial condition and results of operations may be materially adversely affected.

**Increased labor costs could result in exceeding expenses, slow our growth and affect our profitability.**

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, sales and marketing, 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. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused by labor disputes.

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

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;



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- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

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, 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 MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior filing.

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

We are subject to numerous environmental, health, and safety laws and regulations in China and the U.S., including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of discovery, testing, development and manufacturing of our drug candidates. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. We may also be forced to close or suspend operations at certain of our affected facilities temporarily or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects.

We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our drug candidate R&D program efforts. Moreover, there is increasing stakeholder pressure on companies to diligence environmental, social, and governance matters in the supply chain. Negative publicity regarding production methods, alleged practices or workplace or related conditions of any of our suppliers, CROs,

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## RISK FACTORS

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CDMOs or other third parties who perform services for us could adversely affect our reputation and force us to locate alternatives, which could increase our costs and result in delayed supply of components for, and manufacturing of, our drug candidates, or other disruptions to our operations.

In terms of the construction of our manufacturing facilities, they can be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety examine and approve such facilities. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our drug candidates as we plan.

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

We are a relatively small company, operating in China and the U.S. and working on a rich and expanding pipeline of drug candidates. We had a total of 143 full-time employees as of the Latest Practicable Date. Our future financial performance and our ability to commercialize our drug 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 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.

As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on our management, including but not limited to:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- continuing to innovate and develop advanced technology in the highly competitive pharmaceutical industry;
- managing our relationships with third parties, including suppliers and partners;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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 drug 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.

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**We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources, which may negatively impact our R&D progress and overall operations.**

We maintain insurance policies that are required under the PRC laws and regulations and that we believe are in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies cover adverse events in our clinical trials, and we also maintain property loss insurance. We maintain social welfare insurance for our employees in accordance with relevant PRC laws and regulations. However, our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

**We are subject to risks associated with leasing space.**

We lease some of our offices and facilities in China. The lessors of the leased properties may not have valid title or the legal rights to such leased properties or may not have complied with all the necessary property leasing procedures. In addition, as our leases expire, we may fail to obtain renewals, either on commercially acceptable terms or at all, which could compel us to close such offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

Pursuant to PRC laws, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. In practice, as the filing of the lease agreements requires the coordination of both lessors and lessees, we cannot assure you that the lessor will cooperate and complete the registration in a timely manner. Although we have reached out to our lessors for their necessary support with regard to the filing of the lease agreements, as of the Latest Practicable Date, we and our lessors have not filed four of our leases with the governmental authorities due to various reasons, including, without limitation, the failure or unwillingness of the lessors to provide relevant documents. The failure to file and obtain property leasing filing certificates for such leases, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for each agreement not filed, and a maximum fine of RMB40,000 in aggregate. Although non-registration of lease agreements does not in itself invalidate the leases, we may not be able to defend these leases against bona fide third parties, which may negatively affect our ability to operate our business covered under those leases.

**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. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees and business partners were incompliant with any laws or regulations or became involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity. 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.

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## RISK FACTORS

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

Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

Our business could be adversely affected by the effects of epidemics, including COVID-19, avian influenza, severe acute respiratory syndrome (SARS), influenza A (H1N1), Ebola or another epidemic. Any such occurrences could cause severe disruption to our daily operations and may even require a temporary closure of our offices and laboratories. In recent years, there have been outbreaks of epidemics in China and globally. See also “— Key risks relating to our business, business operations, intellectual property rights and financial prospects — The COVID-19 pandemic could adversely impact our business, including our clinical trials.”

### **RISKS RELATING TO OUR DOING BUSINESS IN CHINA**

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

We currently conduct most of our operations in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the benefits we believe are available to us from developing and manufacturing drugs in China.

#### **Changes in U.S. and international trade policies, and in relationships between the PRC and other countries, may adversely impact our business and operating results.**

The U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as imposing several rounds of tariffs affecting certain products manufactured in the PRC. In March 2018, the former U.S. President Donald J. Trump announced the imposition of tariffs on steel and aluminum entering the U.S. and in June 2018 announced further tariffs targeting goods imported from the PRC. Despite the recent re-exemption of U.S. tariffs on some Chinese goods, it remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. It is also unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry.

While we have not started commercialization of any of our drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future drug products, the competitive position of our future drug products, the hiring of scientists and other R&D personnel, and import or export of raw materials in relation to drug development, or may prevent us from selling our future drug products in certain countries. If

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## RISK FACTORS

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any new tariffs, legislation and regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions, such changes could have an adverse effect on our business, financial condition and results of operations.

The existing trade disputes may escalate going forward and may result in certain types of goods, such as advanced R&D equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of relationships between China and the relevant foreign countries or regions. Relationships between the PRC and the relevant foreign countries or regions may therefore adversely affect our business, financial condition, results of operations, cash flows and prospects.

### **Holders of H Shares may be subject to PRC income taxes.**

Holders of H Shares, being non-PRC resident individuals or non-PRC resident enterprises, whose names appear on the register of members of H Shares of our Company, are subject to PRC income tax in accordance with the applicable tax laws and regulations, on dividends received from us and gains realized through the sale or transfer by other means of H shares by such shareholders.

According to the Individual Income Tax Law of the PRC and the Implementation Regulations for the Individual Income Tax Law of the PRC, both came into effect on January 1, 2019, the tax applicable to non-PRC resident individuals is proportionate at a rate of 20% for any dividends obtained from within China or gains on transfer of shares and shall be withheld and paid by the withholding agent. Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (the “**Arrangements**”) executed on August 21, 2006, the PRC Government may levy taxes on the dividends paid by PRC companies to Hong Kong residents in accordance with the PRC laws, but the levied tax (in the case the beneficial owner of the dividends are not companies directly holding at least 25% of the equity interest in the company paying the dividends) shall not exceed 10% of the total dividends.

According to the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on December 29, 2018, and the Implementation Regulations for the Enterprise Income Tax Law of the PRC, which was newly revised and implemented on April 23, 2019, if a non-resident enterprise has no presence or establishment within China, or if it has established a presence or establishment but the income obtained has no actual connection with such presence or establishment, it shall pay an enterprise income tax on its income derived from within China with a reduced rate of 10%. Pursuant to the Arrangements, dividends paid by PRC resident enterprises to Hong Kong residents can be taxed either in Hong Kong or in accordance with the PRC laws. However, if the beneficial owner of the dividends is a Hong Kong resident, the tax charged shall not exceed: (i) 5% of the total amount of dividends if the Hong Kong resident is a company that directly owns at least 25% of the capital of the PRC resident enterprise paying dividends; (ii) otherwise, 10% of the total amount of dividends.

Considering the above, non-PRC resident holders of our H Shares should be aware that they may be obligated to pay PRC income tax on the dividends and gains realized through sales or transfers by other means of the H Shares.

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## RISK FACTORS

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### RISKS RELATING TO THE [REDACTED]

**No [REDACTED] currently exists for our H Shares, and an active [REDACTED] for our H Shares may not develop, especially taking into account that certain of our existing shareholders may be subject to a lock-up period.**

No [REDACTED] currently exists for our H Shares. The initial [REDACTED] for our H Shares to the [REDACTED] will be the result of our negotiations with the [REDACTED] (for themselves and on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the [REDACTED] of the H Shares following the [REDACTED]. We have applied to the Stock Exchange for [REDACTED] of, and permission to [REDACTED], our [REDACTED]. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the H Shares will not decline following the [REDACTED].

In particular, certain part of the H Shares in [REDACTED] as of the date of this Document will be subject to a lock-up period from the [REDACTED], which may significantly affect the liquidity and [REDACTED] of our H Shares in the short term following the [REDACTED]. A [REDACTED] on the Hong Kong Stock Exchange does not guarantee that an active and liquid [REDACTED] for our H Shares will develop, especially during the period when certain portion of our H Shares may be subjected to lock-up, or if it does develop, that it will sustained following the [REDACTED], or that [REDACTED] of the H Shares will rise following the [REDACTED].

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

The [REDACTED] and [REDACTED] of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the [REDACTED] of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] of our H Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] of our H Shares may be highly volatile for specific business reasons, including the following:

- the results of clinical trials of our drug candidates;
- the results of our applications for regulatory approvals of our drug candidates;
- regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters;
- fluctuations in our revenue, earnings, cash flows, investments and expenditures;
- relationships with our suppliers;
- movements or activities of key personnel; and
- actions taken by competitors.

Moreover, shares of other companies [REDACTED] on the Stock Exchange have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in [REDACTED] not directly related to our performance.

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## RISK FACTORS

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

The H Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be not more than five Business Days after their initial [REDACTED] at the [REDACTED]. As a result, [REDACTED] may not be able to [REDACTED] or otherwise [REDACTED] in the H Shares during that period. Accordingly, Shareholders of our H Shares are subject to the risk that the price of the H 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 [REDACTED] or perceived [REDACTED] of our H Shares in the [REDACTED] by major Shareholders following the [REDACTED] could materially and adversely affect the [REDACTED] of our H Shares.**

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

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

We may finance our future cash needs through [REDACTED], licensing arrangements or other collaborations, government funding arrangements, debt financings, or any combination thereof. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our H Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or [REDACTED] additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the [REDACTED] of our H Shares to decline.

**[REDACTED] will experience immediate and substantial dilution as a result of the [REDACTED].**

[REDACTED] will pay a [REDACTED] per H Share in the [REDACTED] that substantially exceeds the per H Share value of our tangible assets after subtracting our total liabilities as of April 30, 2023. Therefore, purchasers of our H Shares in the [REDACTED] will experience a substantial immediate dilution in [REDACTED] net tangible assets, and our existing Shareholders will receive an increase in the [REDACTED] adjusted net tangible assets per Share on their Shares. As a result, if we were to distribute our net tangible assets to the Shareholders immediately following the [REDACTED], [REDACTED] would receive less than the amount they paid for their H Shares. See “Appendix II — Unaudited [REDACTED] Financial Information.”

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## RISK FACTORS

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**Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on [REDACTED] appreciation of our H 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 drug 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 H 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 H Shares will likely depend entirely upon any future [REDACTED] of our H Shares. There is no guarantee that our H Shares will appreciate in value after the [REDACTED] or even maintain the [REDACTED] at which you purchased the H Shares. You may not realize a return on your [REDACTED] in our H Shares and you may even lose your entire [REDACTED] in our H Shares.

**We cannot make fundamental changes to our business without the consent of the Stock Exchange.**

On April 30, 2018, the Hong Kong Stock Exchange adopted rules under Chapter 18A of its Rules Governing the Listing of Securities on the Stock Exchange. Under these rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A. Were any of our competitors that are not [REDACTED] on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

**Facts, forecasts and statistics in this document relating to the pharmaceutical industry may not be fully reliable.**

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources, including information provided or published by government agencies, and we can guarantee neither the quality nor reliability of such source materials. We believe that the information originated from appropriate sources and was extracted and reproduced after taking reasonable care. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, neither we, the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the pharmaceutical industry in and outside China may be inaccurate, and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.



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## RISK FACTORS

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**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.