

RISK FACTORS

You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] our Shares. Our business, financial condition and results of operations could be materially and adversely affected by any of these risks and uncertainties. The [REDACTED] of our Shares could decline due to any of these risks, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to the Sales and Distribution of Our Products

We are largely dependent on sales of a limited number of commercialized products. If we are unable to maintain the sales volume, pricing levels and profit margins for these commercialized products, our profitability could be adversely affected.

We are largely dependent on the sales of our commercialized products, especially our core commercialized products, Vancocin, Ceclor and FPN. Gross revenue from these products (presented as revenue before deduction of sales rebates and sales tax) in aggregate amounted to RMB1,588.1 million, RMB1,799.7 million and RMB1,961.7 million for the years ended December 31, 2020, 2021 and 2022, respectively, accounting for 86.4%, 82.3% and 89.7% of our total gross revenue for the same periods. We expect that sales of these products will continue to comprise a substantial portion of our total revenue in the near future. If we are unable to maintain the sales volumes, pricing levels or profit margins for these products, our profitability could be adversely affected. Many factors could adversely affect sales of our commercialized products, including pricing pressure caused by government policies, other unfavorable government policies, regulatory or enforcement changes, market acceptance within the medical community, inclusion in or removal from the NRDL, medical insurance coverage other than the NDRL, competition with competing products, disruptions or adverse changes in supply chains, manufacturing or distribution, increases in the cost of raw materials, adverse changes in our sales and distribution network, issues with respect to product quality or side effects and disputes over intellectual property. In particular, a substantial portion of certain products we sell to our distributors are then on-sold to public medical institutions in China, which are subject to PRC laws and regulations in relation to the centralized drug procurement scheme and its relevant centralized tender process. The tender process can create pricing pressure among originator-branded products and generic or substitute products, or products that are perceived to be substitute products. In addition, as of the Latest Practicable Date, our Ceclor Sachet, Ceclor Capsules, Zinacef Injection, Zinacef Tablet and Fortum were subject to the regulations in relation to the centralized drug procurement scheme nationwide. For details, see “—Our commercialized products or pipeline products, once approved, may be subject to price adjustments, competition or the centralized tender process, and therefore their prices may decrease, which could materially and adversely affect our financial condition and results of operations.” Moreover, despite our efforts, we may be unable to acquire, develop or commercialize new products that would diversify our business and reduce our dependence on these products.

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Our commercialized products or pipeline products, once approved, may be subject to price adjustments, competition or the centralized tender process, and therefore their prices may decrease, which could materially and adversely affect our financial condition and results of operations.

According to currently effective PRC laws and regulations, the government regulates drug prices mainly by establishing a centralized drug procurement scheme, revising the NRDL and strengthening regulations of medical and pricing practices, including stipulating centralized tender process for drug procurement of public medical institutions. We cannot predict the extent to which our business may be affected by future legislative or regulatory developments. Changes in pricing regulations could limit the prices that we are able to charge for our products, which would adversely affect our revenue, profitability and results of operations. In addition, it is typical that the price of a drug product will decline over the life of the product as a result of, among other things, increased competition from generic and/or substitute products, centralized tender process adopted by public medical institutions, and other pricing policies promulgated by relevant government authorities. Any decreases in the prices of our commercialized products could have a material and adverse effect on our business, financial conditions and results of operations.

A substantial portion of certain products we sell to our distributors are then on-sold to public medical institutions in China. Public medical institutions at all levels are required to procure substantially all of drugs that are covered by the National Essential Drug List or are generally used for common clinical needs through centralized tender process. These drugs are sold to public medical institutions at the successful bid prices in the centralized tender process. The centralized tender process can create pricing pressure among originator-branded products and generic or substitute products, or products that are perceived to be substitute products. If our products are not selected in the bidding process in one or more regions, we will be unable to sell the relevant products to the public hospitals and other public medical institutions in those regions, and our market share, revenues and profitability could be adversely affected. Our commercialized products may not be selected in the bidding process for various reasons, including reduced demand for the relevant product, uncompetitive bidding price, insufficient service quality to meet tender requirements, the relevant product being perceived to be less clinically efficacious than competing products, or our services or other aspects of our operations being perceived to be less competitive.

In November 2018, the PRC government launched the centralized drug procurement pilot scheme for tendering a limited number of drugs with target procurement quantities in 11 cities in China, and subsequently expanded the drug and geographic coverage under the scheme. As of the Latest Practicable Date, the centralized drug procurement scheme covered more than 330 types drugs based on generic names and had a nationwide geographic coverage, according to Frost & Sullivan. The move is aimed at reducing drug prices and may potentially impact how drugs are priced and procured in China. The centralized drug procurement scheme is conducted annually and its drug coverage is updated on an annual basis as well, taking into consideration factors including patient needs, disease prevalence, cost and budget, number of different suppliers of a same generic drug in the market. In addition, according to the current

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regulations, in principle, only originator-branded drugs or reference drugs for the GQCE, along with generic drugs that have passed the GQCE, are eligible to participate in the centralized drug procurement scheme. As of the Latest Practicable Date, according to recent market observations, a type of drug will generally be eligible for inclusion in the centralized drug procurement scheme if there are four or more generic drugs that have passed the GQCE, under the same generic name, according to Frost & Sullivan. According to the same source, as of the Latest Practicable Date, suppliers for drugs included in the centralized drug procurement scheme generally are required to go through a centralized tender process and win the bid in order to sell such drugs. See “Regulations—Overview of PRC Regulations—Regulations in relation to Medical Insurance Program and Centralized Procurement Scheme—The Centralized Drug Procurement in ‘4+7 Cities’ and Nationwide.”

Of the products we sold during the Track Record Period, Ceclor Sachet and Ceclor Capsules, as well as certain other commercialized products, namely, Zinacef Tablet, Zinacef Injection, Fortum and Lipofundin, were subject to the centralized drug procurement scheme nationwide. Our exclusive marketing and distribution agreement for Lipofundin expired on September 30, 2021. The exclusive marketing and distribution agreements for Fortum and Zinacef will expire in December 2023. We did not win the bid to supply our Ceclor Sachet and Ceclor Capsules to public medical institutions nationwide. As a result, while we have sales to other channels that are not restricted by the centralized drug procurement scheme, our sales volume, revenue and market share may be affected.

As of the Latest Practicable Date, the centralized drug procurement scheme was not applicable to two of our core commercialized products, namely Vancocin and FPN, and our recently approved product, Vascepa. Vancocin, one of our core commercialized products with largest revenue contribution during the Track Record Period, has three generic versions that have passed the GQCE as of the Latest Practicable Date, and we cannot guarantee that Vancocin will not be added to the centralized drug procurement scheme in the coming years. FPN, another one of our core commercialized products, currently has no competing generics, but we cannot assure you FPN will not be added to the centralized drug procurement scheme in the coming years as there may be generics that pass the GQCE. In addition, other drugs we sell may be added to the scheme in the future, which may result in increased pricing pressure on us. If our products, such as Ceclor Tablet, Vancocin, FPN and Vascepa, are included in the centralized drug procurement scheme and our competitors win the bids while we fail to do so for our products with the same generic names, demand for our products may decrease, and our sales volume, revenue and market share could be adversely affected. Moreover, even if we win the bid for our products, there may be a significant price reduction or discrepancy between the estimated procurement quantities set out in the tender documents and the actual procurement quantities, and we cannot assure you that the market share of our products will increase. Consequently, there are uncertainties with respect to the impact of the implementation of centralized drug procurement scheme on the sales volume as well as the revenue of drug products. If we cannot achieve targeted sales volumes or sales prices for our products, our business, financial condition and results of operations may be materially and adversely affected.

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In addition, to include any innovative pharmaceuticals in the NRDL, we generally need to undergo a pricing negotiation process with the PRC government. As a result, inclusion of our innovative pipeline products, including Vascepa, Mulpleta and EDP 125, in the NRDL after Vascepa’s commercialization and Mulpleta and EDP 125’s approval for commercialization, may result in a decrease in their targeted price across the country.

Any such or future changes of policies, which we may not be able to predict or control, could create uncertainties that materially and adversely affect our product pricing, and accordingly, our revenue and profitability.

If the prices of our products decline due to government regulations, the emergence of generic or substitute products, or other market factors, we may not be able to mitigate the adverse effects of such price reduction, and our margins and profitability could be materially and adversely affected.

Failure to attain, maintain or expand market acceptance for our products in China’s medical community would have an adverse impact on our operations, profitability and future prospects.

The commercial success of our commercialized products and any pipeline products depends on the degree of market acceptance they achieve in the medical community, particularly among physicians and hospitals in China. As of the Latest Practicable Date, we had three core commercialized products and three core innovative pipeline products. In particular, the market acceptance of our pipeline products will be important to our business operation and financial performance for the foreseeable future. However, physicians may not prescribe or recommend our products to their patients, and procurement departments of hospitals may not purchase our products. The acceptance of any of our commercialized products and pipeline products in the medical community is dependent upon several factors, including:

- the safety, efficacy and indication coverage of our products;
- the products’ perceived advantages and disadvantages relative to competing products or treatments;
- the effectiveness of our efforts to market products to hospitals and physicians;
- the endorsement of our products by KOLs;
- the cost effectiveness of our products;
- the inclusion of our products in the NRDL and the willingness of patients to pay out-of-pocket in the absence of NRDL coverage and/or reimbursement by third-party payers;
- the publicity concerning our products and competing products;
- our ability to respond to changes in needs and preferences of healthcare practitioners;

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- our ability to manage our supply chain to ensure the quality and supply of our products; and
- our collaboration and relationship with our distributors.

If our products fail to attain, maintain or expand market acceptance in the medical community, or if new products introduced by our competitors are perceived more favorable by physicians and patients, the demand for our products may decline and our operations and profitability may be materially and adversely affected.

Certain of our products are off-patent originator-branded drugs that can be manufactured and sold by other pharmaceutical companies in China. If other pharmaceutical companies sell pharmaceutical products substantially similar to ours, our business, financial condition and results of operations could be materially and adversely affected.

Certain of our products, including all of our core commercialized products, are originator-branded drugs that are not protected by compound patents or will no longer be protected by compound patents in the coming years. During the Track Record Period, a substantial portion of our revenue was generated from these originator-branded drugs. Since they are not protected by compound patents or will no longer be protected by compound patents in the coming years, we cannot preclude any third party from offering the same or substantially similar products at more competitive prices. As a result, other pharmaceutical companies may sell equivalent or similar products at a lower price. In addition, with the implementation of the GQCE requirement, generic drugs passing the GQCE may create increased competitive pressure on our originator-branded products. As of the Latest Practicable Date, there were six, one, and six generic versions of Ceclor Sachet, Ceclor Sustained Release Tablets (II) and Ceclor Capsules that have passed the GQCE, respectively. As of the same date, there were three generic versions of Vancocin that have passed the GQCE. Large volumes of sales by other pharmaceutical companies of pharmaceutical products that are equivalent or similar to our products might result in a commensurately large loss in sales of our products, and our business, financial condition and results of operations may be materially and adversely affected.

We may not be able to successfully acquire new commercialized products or in-license new pipeline products of high quality.

We seek to acquire or in-license new products or new promising pipeline products to expand our product portfolio. We acquired the product rights for Ceclor and Vancocin from Eli Lilly in October 2019 and FPN from GSK in May 2020. As of the Latest Practicable Date, we had three in-licensed core pipeline products, namely, Vascepa, Mulpleta and EDP 125. We cannot guarantee that we will be able to continue to successfully identify and acquire commercialized products or in-license new pipeline products with high commercial potential. We cannot assure you that the prospective seller or licensor of products or pipeline products identified by us would agree to sell or license such products or pipeline products to us at favorable commercial terms or at all. In addition, we have limited financial resources, and our resource allocation decisions may lead us to pass on products or pipeline products that may later prove to have high commercial potential and profitable market opportunities. Even if we

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are able to acquire or in-license the products or pipeline products that we target, we cannot assure you that the products or pipeline products will be successfully developed, marketed or commercialized. Moreover, our existing collaborations with our licensors may be harmed or result in litigation or other disputes, and we may not be able to acquire or in-license new products or pipeline products from our current licensors or other global pharmaceutical companies. As a result of these factors, we may not be able to successfully expand our product portfolio and our future growth and prospects may be materially and adversely affected.

Our sales and marketing activities may not be effective and we may not be able to maintain a qualified sales force, which may adversely affect our sales and business prospects.

Successful sales and marketing are crucial for us to increase the market penetration of our products, to expand our coverage of hospitals and other medical institutions, and to promote our new products. As of December 31, 2022, we had approximately 776 sales representatives spanning across 30 provinces in China and covering more than 16,000 hospitals. However, if we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities, our sales and business prospects could be adversely affected.

Our ability to attract, motivate and retain a qualified and professional sales force is important, because we rely on our sales force to promote and market our products. Moreover, we adopted an academic marketing approach. Therefore, our sales and marketing force must possess an adequate academic understanding of a specific therapeutic area, in addition to understanding the attributes and benefits of our products and sufficient promotion and communication skills. If we are unable to provide adequate training and evaluation and maintain a qualified and stable sales force, our sales and marketing may be less successful than desired. We may expand into therapeutic areas for which we have no or limited operational experience. We may not be able to build up the distinct medical knowledge, experience and resources necessary for successful development and sales and marketing in these new therapeutic areas, which may adversely affect our sales and business prospects. Moreover, competition for experienced marketing, promotion and sales personnel is intense. If we are unable to attract, motivate and retain a sufficient number of qualified and professional sales and marketing personnel, sales volumes of our products may be adversely affected, and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

We rely on our distribution network to sell and distribute our products, and if we fail to maintain and expand our distribution network, our business could be adversely affected.

We rely on our distribution network to sell and distribute our products. Our distributors include importers and regional distributors. Importers are primarily responsible for customs clearance and delivery of drugs to regional distributors. Regional distributors are primarily responsible for operating local distribution centers and warehouses, maintaining a sufficient level of inventory and delivery of drugs to hospitals and pharmacies. For details, see “Business—Sales and Marketing—Sales and Distributorship.” Currently, we distribute Ceclor and some of our imported products directly to regional distributors, and we have an importer for Vancocin and FPN.

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Our ability to maintain and grow our business is significantly affected by our ability to maintain and manage a distribution network and to expand our distribution network effectively. The performance of our distributors and their ability to sell our commercialized products and pipeline products, once approved, to expand their businesses and their sales network, and to timely deliver our products may directly affect our sales volume and profitability. Any reduction, delay or cancelation of orders from our distributors and any return of shipments from our distributors (such as due to changes in governmental regulations, product recalls or adverse market conditions), or any material change to our distribution network, including change of our importers, may cause material fluctuations or declines in our revenue or the sustainability of our growth and may have an adverse effect on our business, financial condition and results of operations. For instance, starting January 2020, we no longer sold Zinacef products to the importer appointed by us and decided to act as importer for Zinacef ourselves. From January 2020 to August 2020, the outgoing importer continued to distribute its inventories in China, and meanwhile, we suspended sales of Zinacef and waited for the outgoing importer to clear its inventories to facilitate the transition process. During the pandemic, the outgoing importer took a relatively long period of time to sell out its existing inventories. The regulatory procedures for transition started in the third quarter for Zinacef Injection and the fourth quarter for Zinacef Tablet, respectively, and were substantially completed in December 2020. After the transition procedure in a province was completed, we were able to act as the importer of Zinacef and sell Zinacef directly to regional distributors in that province. According to Frost & Sullivan, such transition timeline and process is in line with industry norm.

Our standard distribution agreement with regional distributors typically has a term of one year. Our importation and distribution agreement with our importer has a term of three years. We and our distributors might elect not to renew the agreements or otherwise terminate our business relationships for various reasons. For example, if price adjustments or other factors substantially reduce the margins our distributors can achieve through the resales of our products to sub-distributors and hospitals or other medical institutions, they may terminate their agreements with us. If any of our major distributors, or a significant number of our distributors, voluntarily or involuntarily suspend or terminate their relationships with us, or if we are otherwise unable to effectively maintain and expand our distribution network, our sales volume and business prospects could be materially and adversely affected.

In addition, we may not be able to offer favorable arrangements to our distributors, and any deterioration in our distributors’ performance may lead to a decline in the productivity and effectiveness of our distribution network and may have a negative impact on our results of operations. We sell our products to distributors at prices agreed between us and the distributors, subject to adjustments based on market conditions. During the course of our collaboration with distributors, we may voluntarily reduce the selling price of our products. We may also have disputes with distributors in the ordinary course of our business. All these factors can all have an adverse effect on our business, financial condition and results of operations.

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We are exposed to concentration risk of reliance on our major distributors, who are our customers.

During the Track Record Period, we generated a significant portion of our revenue from our major customers, which are primarily the importers and regional distributors for our products. For the years ended December 31, 2020, 2021 and 2022, revenue from our five largest customers in each period accounted for approximately 73.1%, 61.3% and 65.6% of our total revenue, respectively. During the same periods, revenue from our largest customer accounted for approximately 55.1%, 54.5% and 57.7% of our total revenue, respectively. Our dependence on a limited number of major customers subjects us to concentration and counter-party risk from our major customers. Specifically, we only have one importer for Vancocin and FPN, our core commercialized products, who resells the products to regional distributors. We cannot guarantee that our major customers will continue to purchase our products or will not reduce or terminate their business with us. Moreover, we cannot guarantee that our major customers will not have a change of business scope or business model in China or will continue to maintain their market position and reputation. Any material adverse change to the operation, financial performance or financial condition of our major customers may have a significant adverse impact on their business with us. If we are unable to find a replacement on comparable commercial terms with similar revenue contribution or distribution qualification and ability within a reasonable period of time, or at all, our business, financial condition, results of operations and profitability may be adversely affected.

We may not be able to effectively manage our distributors or sub-distributors.

We review the performance of our distributors from time to time. However, our ability to manage the activities of our distributors is relatively limited. We mainly rely on our distribution agreements, policies and measures we have in place, to monitor and govern our relationships with distributors, including their compliance with laws, rules, regulations and our policies, as well as their implementation of anti-trust, anti-corruption and anti-bribery measures. However, it is possible that our distributors may take one or more of the following actions, any of which could have a material adverse effect on our business, prospects and reputation:

- failing to distribute our products in the manner we contemplate, impairing the effectiveness of our distribution network;
- breaching our agreements with them, including by selling products that have expired, or by selling products outside their designated territories or to hospitals other than their designated hospitals or engaging sub-distributors;
- failing to manage their supply chains, including logistics, and in turn affecting the distribution of our products;
- failing to maintain the requisite licenses or otherwise failing to comply with applicable regulatory requirements when selling our products; and
- violating anti-corruption, anti-bribery, competition or other relevant laws and regulations.

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Any violation or alleged violation by our distributors of our distribution agreements or any applicable laws and regulations could result in the erosion of our reputation, expose us to liabilities, disrupt our distribution network or create an unfavorable public perception about the quality of our products, resulting in a material adverse effect on our business, financial condition, results of operations and prospects. In addition, our products may also compete with similar products from our competitors sold by our distributors.

Moreover, our distributors, where permitted by applicable laws, regulations and policies, may engage sub-distributors to distribute our products. We do not engage these sub-distributors directly or maintain contractual relationships with them, and we mainly rely on our distributors to manage and control their sub-distributors in accordance with regulatory requirements, the terms of the distribution agreements we entered into with our distributors, and our policies and measures that our distributors agree to comply with. As a result, we have limited control over these sub-distributors. There is no assurance that the sub-distributors will comply with distribution requirements under our distribution agreements. See “Business—Sales and Marketing—Sales and Distributorship—Key Terms of Distribution Agreement.” Furthermore, there is no assurance that we will be able to identify or correct all the sub-distributors’ practices that are detrimental to our business in a timely manner or at all. All these factors may adversely affect our results of operations and reputation, and as there is no contractual relationship between us and these sub-distributors, we have limited legal recourse against them if their activities harm our business or reputation.

If we fail to commercialize our pipeline products, our business prospects could be adversely affected.

Our long-term competitiveness is significantly affected by our ability to commercialize our pipeline products. As of the Latest Practicable Date, we had three core pipeline products, namely, Vascepa, which received NDA approval from the NMPA in May 2023, Mulpleta, for which we have filed NDA and EDP 125, for which we have completed Phase III clinical trial. We also had an additional pipeline product, namely EOC 103. We may be unable to successfully commercialize our pipeline products. Our sublicense agreement for EOC 103 was subject to approval of the original licensor as of the Latest Practicable Date. In addition, as the product development and regulatory approval process is lengthy, the competitive landscape for any pipeline products may change significantly during the development cycle and, as a result, our pipeline products may lose the competitive advantages in pricing, efficacy or other aspects that we had anticipated. Moreover, new pipeline products may be approved for less indications than we had anticipated, which may make the products less valuable or profitable. We might also fail to develop and implement an effective marketing strategy for those products. Furthermore, the successful commercialization of pipeline products also depends on the successful completion of clinical trials and obtaining of regulatory approvals, see “Risks Relating to the Development and Clinical Trials of Our Pipeline Products—If we are unable to successfully complete clinical development and obtain regulatory approvals for our pipeline products, or if we experience significant delays in doing so, we may fail to advance our pipeline products and our business will be materially harmed.” In the event that we fail to successfully commercialize our pipeline products, our business prospects could be adversely affected.

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If we fail to comply with our obligations in the in-licensing arrangements or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose the ability to continue the development and commercialization of our pipeline products.

We have entered into in-licensing arrangements with our licensors to in-license our core pipeline products including Vascepa, Mulpleta and EDP 125. These arrangements provide us with rights to various intellectual property, including rights to use patents and patent applications, and rights to develop, manufacture and commercialize in-licensed pipeline products. We also entered into a sublicense agreement with Taizhou EOC in relation to EOC 103 in 2023. See “Business—Acquisition and In-licensing Arrangements—In-licensing Arrangements.” These in-licensing arrangements impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under our current or future in-licensing arrangements, our licensors may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or commercialize our pipeline products that are covered by the in-licensing arrangements or we may face claims for monetary damages or other penalties under these arrangements. In addition, we cannot assure you that licensors will not breach the relevant in-licensing arrangements. If disagreements or disputes arise between us and our current licensors, the licensors may conclude that we have materially breached the in-licensing arrangements and may terminate the arrangements with us, thereby severely impacting our ability to develop and commercialize the pipeline products. Termination of the in-licensing arrangements, or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or may cause us to lose our rights under these agreements. We may also be involved in claims, disputes and legal proceedings arising from termination of in-licensing arrangements by licensors.

We may need to obtain additional licenses from our existing licensors and other parties to advance our research or allow for manufacture and commercialization of pipeline products. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to spend significant time and resources to redesign our pipeline products or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected pipeline products, which could harm our business, financial condition, results of operations and prospects significantly.

In addition, the agreements under which we license in intellectual property or technology from licensors are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Disputes may arise regarding these agreements, including:

- the scope of rights granted under the agreement and other interpretation-related issues;

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- the extent to which the technology and other intellectual property licensed to us are protected by the intellectual property laws of relevant jurisdictions, including China;
- the extent to which the conduct of our business, including any relevant technology and processes infringe, misappropriate or violate intellectual property of the licensing partner that is not subject to the agreement;
- the potential sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- the priority of invention of patented technology; and
- other commercial terms such as delivery, quality and payment terms.

The resolution of any contract interpretation disagreement that may arise could eliminate or narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected pipeline products, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Failure to obtain or maintain NRDL inclusion for our commercialized products or pipeline products once approved could limit our ability to commercialize, market or sell those products and decrease our ability to generate revenue.

Demand for, prices of, and our ability to successfully commercialize, market and sell any commercialized products and pipeline products once approved depends in part on whether and the extent to which reimbursement for these products and related treatments are covered by reimbursement schemes and national or regional pricing guidelines, which control the prices charged by hospitals. Under the national medical insurance program in China, patients purchasing pharmaceutical products that are listed in the NRDL are entitled to reimbursement for all or a portion of their purchase costs from the social insurance medical fund. Consequently, the inclusion or exclusion of a pharmaceutical product in the NRDL will significantly affect the demand for such product in China. As of the Latest Practicable Date, substantially all of our products, including all of our core commercialized products, had been included in the NRDL. However, the relevant government authorities may, from time to time, review and revise, or change the scope of reimbursement for, the products that are listed in any medical insurance catalog. We cannot assure you that our current products will not be excluded

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from the NRDL. Moreover, we cannot assure you that reimbursement will be available for any pipeline products that we develop upon commercialization. Even if reimbursement is available, the level of reimbursement may not be adequate. Patients in China purchasing drugs included in Category A and Category B of the NRDL are entitled to different reimbursement policies, and therefore the inclusion of a pharmaceutical product in Category A or Category B of the NRDL will significantly affect the entitled reimbursement amount under the NDRL. Reimbursement policies may impact the demand for, or the price of, any commercialized products we market or sell or pipeline products for which we obtain regulatory approval and commercialize. If reimbursement is not available or is available only at limited levels, we may not be able to successfully market and sell our commercialized products or commercialize our pipeline products.

If we fail to maintain our relationships with the MNCs for which we market and sell products, or if the products supplied by such MNCs are not manufactured in compliance with necessary quality standards, our business, financial condition and results of operations may be materially and adversely affected.

During the Track Record Period, we exclusively marketed and sold certain products in China sourced from a limited number of MNCs. If these MNCs fail to supply the products to us, in adequate quantities on a timely basis or at commercial terms acceptable to us, we may lose revenues from such products. In addition, we have no control over these MNCs, including with respect to their regulatory compliance and quality assurance matters. Any delay or interruption of supply related to an MNC’s failure to comply with regulatory or other requirements or for other reasons could limit our ability to generate revenues from such products. Moreover, any manufacturing defect or error discovered after the products have been produced and distributed could result in even more significant consequences, including costly recall procedures, logistics and storage costs, damage to the products’ and our reputation, and potential product liability claims. As a result, our results of operations and business prospects could be materially and adversely affected.

We typically enter into exclusive distribution agreements with these MNCs. Under such agreements, MNCs typically have rights to terminate our exclusive distribution right, or not to renew the agreements when the initial terms expire, under certain circumstances, including if we breach the agreements or we fail to meet the minimum purchase requirements under the distribution agreements. Termination of any of these exclusive distribution agreements could lead to reductions of our revenues and harm our relationships with these MNCs. Furthermore, disputes could also arise between us and these MNCs as to financial or other obligations under our agreements, including our obligation to use commercially reasonable efforts to market and sell the underlying products in China, and we may need to renegotiate or amend our agreements due to circumstances out of our control, such as changes in governmental regulations. These types of disputes and renegotiations could be both expensive and time-consuming to resolve and may result in disruption in the sale of our products or damage our relationships with these MNCs.

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We operate in a highly competitive environment and we may not be able to anticipate the market opportunities for our pipeline products or compete effectively against current and future competitors.

The pharmaceutical market in China is highly competitive and is characterized by a number of established, large pharmaceutical companies, as well as some smaller emerging pharmaceutical companies. We compete with MNCs that have operations in China. We also face competition from other pharmaceutical companies engaged in the research, development, production, marketing or sales of pharmaceutical products, especially from those in our core therapeutic areas, namely anti-infectives, CVD and respiratory system diseases, as well as in our other therapeutic areas. Our inability to compete effectively could result in decreases in sales, reduction of price and loss of market share, any of which could have a material adverse effect on our results of operations and profit margins. Furthermore, our products compete with other similar products or treatments for which our products are indicated. Moreover, if we fail to control our production costs or strengthen our quality control efforts, we may lose our market share. If we are unable to maintain our products’ leading market positions, our business, financial condition, results of operations and prospects may be materially and adversely affected.

The pharmaceutical industry is characterized by rapid changes in science, technology, constant enhancement of industrial know-how and frequent emergence of new products or treatment options. Future technological improvements and continuous product developments in the pharmaceutical industry may render our products obsolete or decrease our viability and competitiveness. Therefore, our future success will largely depend on our ability to adapt to the constantly evolving industry landscape, and to launch new products that meet evolving market demand, in particular, new products that are effective in diagnosing and/or treating diseases and illnesses. If we fail to introduce new or improved products which meet the requirements of the changing market, or if our new or improved products do not achieve adequate market acceptance, our business prospects may be materially and adversely affected.

Clinical demand for pharmaceutical products may change rapidly. Our success depends on our ability to anticipate product offering lead-time and demand, identify customer preferences and adapt our products to these preferences. We may need to adjust our research and development plan, production scale and schedule, product portfolio, and inventory levels based on customer demand, sales trends and other market conditions. We estimate the incidence and prevalence of target patient populations for particular diseases based on various third-party sources, such as scientific literature, surveys of clinics, patient groups or market research, as well as internally generated analysis. We use such estimates in making decisions regarding our product acquisition or in-licensing strategy and product development strategy, including determining which pipeline products to focus our resources on for research and development. These estimates may be inaccurate or based on imprecise data and thus may substantially deviate from actual market conditions. The total addressable markets’ opportunities will depend on, among other things, acceptance of our drugs by the medical community, patient access, drug pricing and reimbursement policies. The number of patients in the addressable markets may turn out to be lower than we expect, patients may not be

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amenable to treatment with our products, or new patients may become increasingly difficult to identify or access. Furthermore, new studies could change the estimated incidence or prevalence of the diseases that our product candidates target, and the number of addressable patients for our product candidates may turn out to be lower than expected. There can be no assurance that we will be able to sufficiently and promptly respond to changes in market demand in the future, and such failure may have a material and adverse effect on our business, financial condition, results of operations and profitability. In addition, we may obtain approval for indications for our product candidates that are not as broad as we intend. In such cases, even if we managed to obtain significant market shares or the required governmental approval for our pipeline products, our financial condition and results of operations may be materially and adversely affected because the potential target populations are smaller than we anticipated.

Many of our competitors, including MNCs and domestic pharmaceutical companies that market and sell competing products in major addressable markets of our commercialized products and pipeline products in China, may have substantially greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we have. Certain of our competitors may be actively engaged in research and development in areas where we have products or where we are developing pipeline products or new indications for our products. Other companies may discover, develop, acquire or commercialize products more quickly or more successfully than we do. There may also be significant consolidation in the pharmaceutical industry among our competitors, or alliances developed among competitors that may rapidly acquire significant market share. If we fail to effectively compete with our competitors or adjust to structural changes in the pharmaceutical industry, our operations and profitability may be materially and adversely affected.

Drug adverse reactions and negative results from off-label promotion of our products could materially harm our reputation, the product brand name and our results of operations and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug promotion. Off-label drug promotion is promoting 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 and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the off-label promotion and we have implemented internal compliance policies strictly prohibiting the off-label promotion of our products, there remains the risk that our product is subject to off-label drug promotion and is prescribed in a patient population, dosage, or dosage form that has not been approved by competent authorities. Occurrence of off-label drug promotion may render our products less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including the Company’s [REDACTED]. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

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Counterfeits of our products could negatively affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system may be inadequate to eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode our sales volume of the relevant products. Moreover, counterfeit products may or may not have the same chemical composition as our products, which may make them less effective than our products, entirely ineffective or even cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. The existence and prevalence of counterfeit pharmaceutical products, products of inferior quality and other unqualified products in recent years from time to time may reinforce the negative image in general of all pharmaceutical products manufactured in the PRC or other relevant markets among consumers, and may harm the reputation and brand names of companies like us. As a result of these factors, the continued proliferation of counterfeit pharmaceutical products in the market could affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims.

Risks Relating to the Manufacture and Supply of Our Products

We rely on certain third-party CMOs and suppliers for our products, as a result, our business could be harmed if those third parties fail to provide us with sufficient quantities of products or fail to do so at acceptable quality levels, lead time or prices.

We currently engage certain third-party CMOs and suppliers for our core commercialized products. For example, we rely on third parties to supply APIs, raw materials, semi-finished products or finished products for Vancocin, finished products for FPN and APIs for Ceclor. We may also rely on certain third-party CMOs and suppliers for raw materials and production of our core pipeline products when commercialized in the future, such as Vascepa and Mulpleta. Reliance on third-party manufacturers and suppliers would expose us to the following risks:

- we may be unable to identify CMOs or suppliers on acceptable terms or at all because the number of potential manufacturers and suppliers for APIs is limited and the NMPA or other comparable regulatory authorities must evaluate and approve any manufacturers as part of their regulatory oversight of our products;
- our CMOs or suppliers might be unable to manufacture or supply sufficient APIs, raw materials, semi-finished products or finished products for our products, or produce the quantity and quality required to meet our commercial needs in a timely

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manner, due to reasons such as regulatory requirements or actions, adverse financial developments of the CMOs or suppliers, unexpected demand and/or labor shortages or disputes, resulting in constraint on our supply chain;

- our procurement from foreign suppliers involves export and import processes which may cause significant delay due to factors out of our control, such as declaration, drug inspection, customs clearance, inspection and quarantine;
- our CMOs and suppliers are subject to ongoing periodic spot check by the regulatory authorities. We do not have control over CMOs’ and suppliers’ compliance with these regulations and requirements;
- we may not be able to renew our agreements with our CMOs and suppliers, or our agreement with those CMOs and suppliers may be terminated for various reasons;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our CMOs or suppliers in the manufacturing process for our pipeline products;
- our CMOs and suppliers may not properly obtain, protect, maintain, defend or enforce our or our licensors’ intellectual property rights or may use our or our licensors’ 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;
- geopolitical conditions, trade war, regulatory embargoes and policy changes on importation and exportation between different countries (including China, the U.S. or other countries) may result in delays or shortages in the supply of our raw materials and finished products;
- our CMOs and suppliers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- raw materials and components provided by our CMOs and suppliers for our manufacturing process may not be available or may not be suitable or acceptable for use due to material or component defects;
- our CMOs or suppliers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments;
- our CMOs or suppliers may be subject to natural or man-made disasters, epidemics, hostilities, social unrest, and other factors out of their control that disrupted their business operations; and
- our manufacturing costs may fluctuate due to movements in foreign exchange rates as we work with overseas CMOs and suppliers.

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Each of these risks could result in higher costs or adversely impact commercialization of our products. A reduction in, or lack of availability of, any supplies, or interruptions in the supply chain, may impact our profitability to the extent that we are required to pay higher prices for, or are unable to secure adequate supplies of, the necessary CMO services or raw materials. We may not be able to transfer the increasing costs of CMO services and raw materials to our customers in a timely manner, or at all, and may thus increase our cost of sales and negatively affect our profit margins and, more generally, our business, financial conditions, results of operation and prospects. In addition, a change in suppliers could require us to exercise significant efforts or make investments, in circumstances where the items or services supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on us. Although we work closely with CMOs and suppliers to monitor and prevent unfavorable conditions, these efforts may not be successful. Moreover, if we change suppliers for APIs, we may need to obtain relevant approval from the NMPA. We cannot assure you we would obtain such approval in a timely manner, or at all. Changes in suppliers for API could also make our products lose their qualifications as originator-branded drugs, which could have a material adverse effect on our business. Furthermore, we may not be able to identify suitable replacement on reasonable terms or at all if such supply was subsequently found to not be in compliance with our quality standards or resulted in quality failures or product contamination. As a result, our ability to satisfy demand for our products could be harmed, which could materially and adversely affect our business operation and operating results.

If we suffer substantial disruption to any of our manufacturing facilities, or encounter problems in manufacturing our products, our business and results of operations could be adversely affected.

Our finished Ceclor products are manufactured in our manufacturing facility located in Suzhou, which was acquired from Eli Lilly in October 2019. We are also planning to manufacture FPN in-house. The operation of manufacturing facilities and our production safety may be substantially interrupted and materially and adversely affected due to a number of factors, many of which are outside of our control. These may include fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, IT system and business support system breakdowns, upgrades, updates or replacement, terrorist attacks and wars, or other natural disasters and disease outbreaks, as well as loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities or changes in relevant laws and regulations. Moreover, our track record of Ceclor production is relatively short and we have limited experience in manufacturing FPN in-house. We rely on manufacturing technologies and know-how transferred from independent third parties, and if we fail to maintain any manufacturing technologies and know-how due to any reason, our production may also be substantially interrupted.

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If the operation of our manufacturing facility is substantially disrupted, we may not be able to replace the equipment or inventories at such facility, or find substitute third-party contractor to continue our manufacturing in a legal, timely and cost-effective manner or at all. Although we maintain property insurance covering our manufacturing facilities and equipment that we believe are sufficient in accordance with customary industry practice, the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to any of our manufacturing facility. Problems may also arise during manufacturing for a variety of reasons, including failure to maintain a stable production team or retain our experienced manufacturing employees with production know-how, equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, facility maintenance, delays related to the construction of new sites or the expansion of our existing manufacturing facility, limits to manufacturing capacity due to regulatory requirements, changes in the types of products manufactured, physical limitations that could inhibit continuous supply, man-made or natural disasters, and environmental factors. As a result of disruption to any of our manufacturing facility or any problems in manufacturing our products, we may fail to fulfill contract obligations or meet market demand for our products, and our business, revenues and profitability could be adversely affected.

If we fail to increase our manufacturing capacity, our business growth could be adversely affected.

We plan to increase our manufacturing capacity to be able to continue growing our commercialization scale and meet market demand. Capacity expansion will require significant capital investment and be subject to a number of risks and uncertainties, including our ability to obtain the requisite permits, licenses and approvals for the construction and operation of the new manufacturing facilities and production lines. In addition, manufacturing expansion and upgrade plans may take years to complete, and the regulatory approval process can be relatively lengthy and subject to factors out of our control. We have plans to expand the manufacturing capacity for our Ceclor products, which we manufacture ourselves. The manufacturing utilization rate for our Ceclor Sachet and Ceclor Sustained Release Tablets (II) for the year ended December 31, 2022 was 91.7%, and 88.1%, respectively. We also have plans to expand the manufacturing capacity for our FPN going forward. If we are unable to increase our manufacturing capacity, we may not be able to capture the expected growth in demand for the relevant products, which could adversely affect our business prospects. There can be no assurance that we will be able to increase our manufacturing capacities in time or in the manner we contemplate, or at all.

If our products are not manufactured in compliance with the necessary quality standards, our business and reputation could be harmed, and our revenue and profitability could be adversely affected.

Our products and manufacturing processes, including those of our own manufacturing facilities and our CMOs, are required to meet high quality standards. This is especially the case for our core commercialized products, which are originator-branded drugs and the reference drugs for the GQCE in China. The NMPA and other comparable regulatory authorities may also conduct inspections as required by relevant laws and regulations. Despite our quality control

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system and standard operating procedures and our CMOs’ quality assurance measures to help prevent quality issues in respect of our products, we cannot eliminate the risk of errors, defects or failure. We may fail to detect or resolve quality defects in our manufacturing process or ensure our CMOs’ compliance with our quality standards as a result of a number of factors, many of which are outside our control, including:

- manufacturing errors;
- technical or mechanical malfunctions in the manufacture process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and
- quality issues with the raw materials we purchase or produce.

In addition, if we expand our manufacturing capacity in the future, we may not be able to ensure consistent quality between products manufactured in the existing and new facilities, or need to incur substantial costs for doing so. Furthermore, if we acquire other manufacturing facilities, we may not be able to immediately ensure that such manufacturing facilities and procedures will meet our own quality standards.

Failure to detect quality defects in our products or to prevent such defective products from being delivered to end-users could result in patient injury or death, product recalls or withdrawals, license revocation or regulatory fines, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenues and profitability.

Failure to effectively manage our supply chain could increase our operating costs, or result in manufacturing delays that lead to unfulfilled customer orders, either of which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our operations significantly depend on our ability to manage our supply chain effectively to successfully meet our customers’ demand while exposing us to low inventory risk. However, as a result of rapidly changing market demand, fluctuation in the supply market and the volatile economic environment globally, there can be no assurance that we are able to continue to manage our supply chain, such as manage CMOs, suppliers and logistic service providers, especially those outside China, effectively. Further, demand for products could change significantly between the time when the products are ordered and the time when they are ready for delivery. It also is particularly difficult to forecast product demand accurately when we begin to sell a new product. If we underestimate demand for our products, we may experience inventory shortages which may, in turn, result in unfulfilled customer orders, leading to a negative impact on our customer relationships. Conversely, overestimated demand for our products by us could adversely affect our cash flows, cash positions and financial conditions. There can be no assurance that we will be able to maintain proper inventory levels for our products, and any such failure may have a material and adverse effect on our business, financial condition, results of operations and prospects.

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We have limited experience in manufacturing our products and pipeline products on a large scale.

Our experience in drug manufacturing is limited. Currently, we manufacture Ceclor products by ourselves but our track record of Ceclor production is relatively short. We also plan to manufacture FPN by ourselves. We built our FPN manufacturing facility and transferred certain technologies from GSK in 2022. Although we are able to leverage such transferred manufacturing technologies and know-how for FPN, we have limited experience in manufacturing FPN in-house. The manufacture of pharmaceutical products is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the potential expansion of our manufacturing facility, limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made errors or omissions, natural disasters, and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to 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 of products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

We may fail to adequately manage our inventory.

We are required to maintain proper finished product and raw material inventory levels in order to satisfy demand coming from our extensive distribution network and successfully meet our customers’ demand. However, we are exposed to inventory risk as a result of changes in product life cycles, changing clinical demands, license renewals, uncertainty of product developments and launches, system upgrades, as well as the volatile economic environment in China. There can be no assurance that we can accurately predict these trends and events and avoid over-stocking or under-stocking our products and raw materials. Further, demand for products could change significantly between the time when the products are ordered and the time they are ready for delivery. When we begin to sell a new product, it is particularly difficult to forecast product demand accurately.

We have implemented an inventory management system that monitors each stage of the warehousing process. Our supply chain management team is responsible for providing rolling forecast and placing orders to CMOs and suppliers for our products and raw materials based on our forecast of market demands and estimated safe inventory level for our products and raw materials. However, we may be unable to sell or utilize such inventory in a timely manner or at all. Inventory levels in excess of demand may result in inventory write-downs, expiration of our products and raw materials or an increase in inventory holding costs and a potential negative effect on our liquidity. In addition, if we underestimate demand, we may experience inventory shortages which may, in turn, result in unfulfilled customer orders, leading to a negative impact on our customer relationships. There can be no assurance that we will be able to maintain proper inventory levels of our products and raw materials, and any such failure may have a material and adverse effect on our business, financial condition, results of operations and prospects.

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Risks Relating to the Development and Clinical Trials of Our Pipeline Products

If we are unable to successfully complete clinical development and obtain regulatory approvals for our pipeline products, or if we experience significant delays in doing so, we may fail to advance our pipeline products and our business will be materially harmed.

Our business growth will be affected by our ability to develop, obtain regulatory approvals and commercialize our pipeline products in time or at all. Vascepa received NDA approval from the NMPA in May 2023. In addition, we submitted NDA to the NMPA for Mulpleta (for the treatment of CLD-associated TCP) in November 2021, and have completed the Phase III clinical trial for EDP 125 (for the treatment of ADHD in children and adolescents) in 2023. We have invested significant efforts and financial resources in our existing pipeline products. The success of our pipeline products will depend on several factors, including:

- successful patient enrollment in, and completion of, clinical trials;
- the performance by CROs, or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining sufficient supplies, including, where applicable, suppliers from our in-licensors, that may be necessary for use in clinical trials for evaluation of our pipeline products;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals in a timely manner for the development and commercialization of our pipeline products;
- developing sufficient commercial manufacturing capabilities;
- successfully launching commercial sales of our pipeline products, if and when approved;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our innovative pipeline products;
- ensuring that we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- gaining competitive advantage over other pipeline products and products; and
- continued acceptable safety profile for our pipeline products following regulatory approval, if and when received.

If we experience difficulty in one or more of these factors, we may not be able to commercialize our pipeline products in time or at all. Our business may be materially harmed as a result and we may not be able to generate sufficient revenues and cash flows to continue our operations.

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There can be no assurance that our clinical development activities will be completed as planned or at all or that we will make regulatory submissions or receive regulatory approvals as planned after completion of clinical trials or that we will be able to adhere to our current schedule for the launch of any of our product candidates. In addition, we are subject to various product development milestone payments under the licensing agreements of our pipeline products. See “Business—Acquisition and In-licensing Arrangements—In-licensing Arrangements.” If we fail to achieve one or more of these milestones as planned, it could adversely affect our business prospects.

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

The timely completion of a clinical trial in accordance with its protocol depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population, the size of the study population required for analysis of the trial’s primary endpoints, the patient eligibility criteria defined in the protocols, the design of the trial, and patients’ possible inability to complete a clinical trial. Our clinical trials will be likely to compete with other clinical trials for pipeline products that are in the same therapeutic areas as our pipeline products. The competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect that some of our clinical trials may be conducted at the same clinical trial sites that some of our competitors use, which may reduce the number of patients available for our clinical trials at such clinical trial sites. Patient enrollment may also be delayed as a result of epidemics or similar events. This may, among other things, result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our pipeline products.

Drug development involves a lengthy and expensive process with an uncertain outcome, and unsuccessful clinical trials or procedures relating to products under development or products to be developed under any indication expansion plan could have a material adverse effect on our prospects and financial condition.

Before obtaining regulatory approval to market our pipeline products, drug developers must conduct substantial pre-clinical research and conduct extensive clinical trials to demonstrate their safety and efficacy in humans. As of the Latest Practicable Date, we had submitted NDA to the NMPA for Mulpleta and were preparing NDA submission of EDP 125. As of the same date, the NDA of EOC 103 had been submitted to the NMPA by Taizhou EOC. We also have certain indication expansion plans for our pipeline products, such as Vascepa and Mulpleta. Clinical trials are expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the research and development process. The results of preclinical research and early clinical trials of our pipeline products

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may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Pipeline products in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding positive results in earlier trials. Likewise, our future clinical trial results may not be favorable despite obtaining positive results in earlier trials. Any unsuccessful clinical trials or procedures relating to products under development or products to be developed under any indication expansion plan could also adversely affect our financial condition as financial resources we devoted to such products cannot be recuperated.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our pipeline products.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to complete the clinical trials, receive regulatory approval or commercialize our pipeline products, including:

- regulators may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- access to trial sites may be temporarily unavailable due to various factors, some of which may be beyond our control;
- clinical trials of our pipeline products may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- our pipeline products, or the substance of our pipeline products, may prove to cause adverse events, have undesirable side effects or other unexpected characteristics, causing us to suspend or terminate the trials or bear large compensation for personal injury;
- our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

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- our other third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- clinical trials of our pipeline products may produce negative or inconclusive results, and additional clinical trials or abandoning product development programs may be required;
- the number of patients required for clinical trials of our pipeline products may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- we might have to suspend or terminate clinical trials of our pipeline products for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;
- regulators may require us to suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements;
- the cost of clinical trials of our pipeline products may be greater than we anticipate; and
- the supply or quality of our pipeline products, companion diagnostics or other materials necessary to conduct clinical trials of our pipeline products may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our pipeline products beyond those that we currently contemplate, or if we are unable to successfully complete clinical trials of our pipeline products or other testing, we may be delayed in obtaining regulatory approval for our pipeline products or not obtain regulatory approval at all.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our pipeline products or allow our competitors to bring products to market before we do. This could impair our ability to commercialize our pipeline products and may harm our business and results of operations.

We rely on third parties to monitor, support and/or conduct clinical trials of our pipeline products. If these third parties do not duly carry out their contractual obligations or meet expected deadlines, we may not be able to obtain regulatory approvals for or commercialize our pipeline products and our business could be harmed.

We have relied upon and plan to continue to rely upon third-party CROs to generate, monitor or manage data for our ongoing and future research and development programs. We rely on CROs and clinical investigators for execution of our 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 reliance on the CROs and clinical investigators does not relieve us of our regulatory responsibilities. Although we procure insurance for the

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clinical trials, the coverage of the insurance may not be sufficient to cover all of the losses or claims that we face. We, our CROs for our clinical programs, and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA and other comparable regulatory authorities for all of our products in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications or even suspend our clinical trials. In addition, our clinical trials must be conducted with products 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 is terminated, we may not be able to find appropriate replacements or enter into arrangements with alternative CROs on commercially reasonable terms in a timely manner. Switching or adding CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. In addition, those who work for our CROs are not our employees. Except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs do not duly 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 pipeline products. As a result, our results of operations and the commercial prospects for our pipeline products would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our future revenue growth is affected by our ability to work effectively with CROs and clinical investigators to develop our pipeline products, including obtaining regulatory approvals. Our arrangements with CROs and clinical investigators will be critical to successfully bringing products to market and commercializing them. We rely on CROs and clinical investigators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our CROs and clinical investigators. Therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If third parties fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We cannot guarantee the satisfactory performance of any of our CROs and clinical investigators and if any of our CROs and clinical investigators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.

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

As we have limited human and financial resources, we must limit our research and development programs to specific pipeline products that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other pipeline products or for other indications that later prove to have greater commercial potential. We cannot assure you our strategies will ultimately turn out to be advantageous. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Such developments could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Extensive Government Regulation

The pharmaceutical industry in China is highly regulated. Compliance with relevant laws, rules, government regulations or industry practices, including the healthcare reform in China, and their changes, may result in additional costs.

The pharmaceutical industry in China is highly regulated. Changes in laws, rules, government regulations or in practices relating to the pharmaceutical industries, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may cause difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects. Our licensors and other MNCs gain exposure to the China market through in-license arrangements or distribution agreements with us. During the Track Record Period, we exclusively marketed and sold certain drug products in China and provided marketing and promotion services for some MNCs. We have also acquired drug products and in-licensed pipeline drug products from some MNCs. Furthermore, our business operation is also subject to other PRC regulations, including regulations in relation to the centralized drug procurement scheme, the “two-invoice” system, the marketing authorization holder system, the import of drugs and data privacy. Regulators have changed and may continue to change these regulations. For example, the centralized drug procurement scheme was launched in November 2018 by the PRC government for tendering only a limited number of drugs with target procurement quantities in 11 cities in China. However, subsequently, the centralized drug procurement scheme has been continuously expanded both in terms of the number of drugs covered and geographic coverage. In addition, after the implementation of the two-invoice system, a maximum of two invoices between a manufacturer and hospital are allowed, each manufacturer will sell to a distributor and that distributor will be required to sell directly to hospitals, eliminating multi-tiered distribution. The two-invoice system has had a significant impact on circulation of pharmaceutical products. If China modifies regulations which materially and adversely affects our collaboration with MNCs or other regulations relevant to us, our business, financial condition, results of operations and prospects may be materially and adversely affected as well.

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Our products may fail to comply with ongoing regulatory requirements applicable to us.

Our commercialized products are, and any pipeline products, once approved, will be, subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy and other post-market information, and other requirements of regulatory authorities in China and/or other countries.

We, our CMOs, the relevant MNCs for whom we distribute products, and relevant manufacturing facilities are required to comply with extensive regulatory requirements from the NMPA and/or other comparable authorities. As such, we are and will be subject to continuous review and inspections by the regulators in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA or other authorities. Accordingly, we must continue to devote time, money and effort in all areas of regulatory compliance and may be adversely affected by any non-compliance of our CMOs or the relevant MNCs.

The regulatory approvals for our products are, and any approvals that we receive for our pipeline products may be, subject to limitations on the indicated uses for which our product may be marketed. The approvals we obtain may also be subject to other conditions which may require potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of our products or drug candidates. Such limitations and conditions could adversely affect the commercial potential of our products.

The NMPA or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if we, our CMOs or the relevant MNCs fail to maintain compliance with these ongoing regulatory requirements or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our products or product candidates or with our manufacturing processes may result in revisions to the approved labeling or requirements to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls. For example, one of the products we distributed for an overseas pharmaceutical company during the Track Record Period was recalled due to non-material product defects;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our products and pipeline products; and/or
- injunctions or the imposition of civil or criminal penalties.

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The NMPA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products placed on the market. Products may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the NMPA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our pipeline products. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or abroad, where the regulatory environment is constantly evolving. 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 unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

We and our business partners may fail to obtain or renew certain approvals, licenses, permits and certificates required for the development, production, sales and distribution of our products or fail to comply with relevant regulations and industry standards.

The pharmaceutical industry is subject to extensive government regulation and supervision. We are governed by various local, regional and national regulatory regimes in various aspects of our operations, including licensing and certification requirements and procedures for manufacturers of pharmaceutical products, operating and safety standards, as well as environmental protection regulations. There can be no assurance that the legal framework, licensing and certification requirements or enforcement trends in our industry will not change in a manner that may result in increased costs of compliance, or that we will be successful in responding to such changes. In addition, we are subject to the risk of adverse changes to favorable policies from which we currently benefit, and the introduction of unfavorable policies. The costs we incurred to comply with these laws and regulations, including those related to environmental protection, may materially increase our total costs and reduce our profit. Any violation of these laws, rules or regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our production facilities and obligations to take corrective measures.

We are also required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. Third parties, such as distributors, CROs and CMOs, on whom we may rely to develop, produce, promote, sell and distribute our products may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates, subject us to penalties, and increase our compliance costs. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates.

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Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. We may also fail to comply with other relevant laws and regulations related to our operations including our investments. Furthermore, if the interpretation or implementation of existing laws and regulations (including those in relation to product approval, sales, manufacturing, labor, health and safety, and tax) change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, decrease our revenues and increase our costs, which could materially reduce our profitability and prospects.

Our IDL licenses are subject to periodic renewal and may be updated from time to time, which process of the IDL licenses could be prolonged. As a result, our purchases and sales could be temporarily increased prior to the IDL license renewal or updating and temporarily decrease during the renewal or updating periods.

We hold the IDL licenses for our imported core commercialized products, namely Vancocin and FPN. In addition, the MNCs to whom we acted as an exclusive marketer and distributor hold relevant IDL licenses for imported drugs. The term of an IDL license is five years in China. In order to renew an IDL license, the holder need to submit a renewal application to the CDE at least six months prior to the expiry of the IDL license. The CDE will conduct post-marketing evaluation and adverse drug reaction monitoring, review the change of information stated in the drug approval certificates and carry out other relevant procedures as required under the drug certificates and by the NMPA. If all requirements for the license renewal have been satisfied, a drug re-registration approval notification will be issued. In addition, if any information in the IDL license needs to be updated, the holder of an IDL license should update such changes with the NMPA according to relevant applicable laws and regulations. See “Regulations—Regulations in Relation to the Registration of New Drugs—Re-registration and Change of the Registration for Post-Marketing Drugs” for details. The review process of the NMPA and other relevant authorities could be prolonged, and we cannot assure you that we or relevant MNCs can renew and update the IDL licenses in a timely manner, or at all. In the past, in order to use our best efforts to avoid supply shortage of our products, we, out of caution, temporarily increased our purchases and sales according to the increased purchase orders we received from our importers prior to the IDL license renewal or updating, and our purchases and sales therefore temporarily decreased during the IDL license renewal or updating periods as our importers placed fewer purchase orders. For example, due to a change of a CMO for Vancocin packaging, we submitted relevant IDL change application with the NMPA in the first quarter of 2021 to update the information of the packaging plant in our IDL license for Vancocin, and we, out of caution, temporarily increased our purchases and sales of Vancocin according to the purchase orders placed by our importer prior to the IDL license updating, and our purchases and sales of Vancocin therefore temporarily decreased during the IDL license updating period. We completed the IDL license update in February 2021.

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We face regulation and potential liability related to privacy, data protection and information security which may require significant resources and may adversely affect our business, operations and financial performance.

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, 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. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance including, for example, substantial operational costs associated with changes to our data processing practices. Failure to comply with any of these laws could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In recent years, the PRC government has promulgated an increasing number of laws and regulations governing the various aspects of information security, data collection and privacy protection, including, among others, the Cybersecurity Law of the PRC (《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, and 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. Under the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), prior consent shall be obtained from the individual when personal information is being processed, unless explicitly permitted under certain circumstances. Furthermore, any data processing activities in relation to 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 strict protective measures have been taken. Certain industry-specific laws and regulations may also affect the collection and transfer of personal data in China, including Administrative Regulations on Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our clinical trial practices, potentially resulting in the confiscation of human genetic resources samples and associated data and administrative fines. Such 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 could be held liable for the damage caused. In addition, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from

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misconduct or negligence. Furthermore, our clinical trials frequently also involve professionals from third-party institutions working with our staff and enrolled subjects. We cannot ensure that such persons will always comply with the applicable laws and regulations or our data privacy measures. We also cooperate with third parties including hospitals, CROs 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 a result of our failure. Any change in the applicable laws and regulations could affect our ability to use medical data and subject us to liability for the improper use of such data. 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.

Risks Relating to Our Intellectual Property Rights

Our rights to develop and commercialize our in-licensed pipeline products are subject, in part, to the terms and conditions of licenses granted to us by our licensors.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of our pipeline products and certain of these third parties from which we have been granted licenses themselves rely on licenses from other third parties. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our pipeline products. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses. In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the pipeline products for which we have been granted license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have in-licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such in-licensed rights could be adversely affected.

In spite of our best efforts, our licensors might conclude that we have materially breached our in-licensing agreements and might therefore terminate the in-licensing agreements, thereby removing our ability to develop and commercialize products covered by these in-licensing agreements. If any of our licensors goes bankrupt, some or all of our rights under the licensing agreements may be rejected during the bankruptcy proceeding. See “Business—Collaboration with Licensors.” As such, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to

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receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We depend on patents, trademarks, trade secrets, know-how and other forms of intellectual property protections for certain of our products and pipeline products, but these protections may not be adequate and we may not be able to prevent unfair competition by third parties.

We rely on a combination of patent, trademark, trade secrets, know-how and other forms of intellectual property protections for certain of our products and pipeline products to protect our intellectual property. As of the Latest Practicable Date, we owned 20 PRC patents. Additionally, we in-licensed ten granted PRC patents and 18 filed PRC patent applications from our licensors in connection with our in-licensed pipeline products as of the Latest Practicable Date. We also rely on unregistered proprietary rights, including know-how and trade secrets related to development, manufacturing and commercialization of our products and pipeline products. Confidentiality agreements entered into between us and our employees and other third parties prohibiting them from disclosing proprietary information or technology may not provide meaningful protection for us, and may not effectively prevent leakage or unauthorized disclosure of trade secrets and other proprietary information. Third parties who are not party to our confidentiality agreements may obtain access to our trade secrets or know-how. Our competitors may independently develop similar or equivalent trade secrets or know-how. The disclosure or use of our intellectual properties or technologies by third parties, including our competitors, could reduce or eliminate any competitive advantage we have developed, cause us to lose sales opportunities or otherwise harm our competitive position, which could have a material adverse effect on our business, financial condition and results of operations.

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, for our commercialized products, we rely on our trademarks to differentiate us from our competitors, and as a result, if we are unable to prevent third parties, including our distributors, from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to products, which could make it difficult for us in those jurisdictions to defend the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including lack of novelty or inventiveness of the underlying invention, or other known or unknown deficiencies in the patents or patent applications. We may also fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements or include such

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provisions in our relevant agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, advisers and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries. Patent applications in China and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all.

Under the Patent Law of the PRC (中華人民共和國專利法) promulgated by the Standing Committee of the NPC, as amended, patent applications are maintained in confidence until their publication at the end of 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and the date on which patent applications were filed. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions. Furthermore, China 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, if a third party can establish that we or our licensors were not the first to file for patent protection of such inventions, our owned and in-licensed patent applications may not issue as patents and even if issued, may be challenged or invalidated or ruled unenforceable. In addition, under PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we in-license or own currently or in the future are to be issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of 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. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC and other countries. We may be subject to a third-party pre-issuance submission of prior art to the CNIPA or other related intellectual property offices, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or pipeline products and compete directly with us without payment to us. Moreover, we may have to participate in interference proceedings declared by the CNIPA or other related intellectual property offices to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our

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invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and pipeline products. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or pipeline products will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Patent Law of the PRC was amended on October 17, 2020 and came into effect from June 1, 2021, which may have potential impact on our existing patent rights and future patent applications. We also cannot guarantee that other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection. Moreover, changes in other laws and regulations in our target markets, as well as changes in the geopolitical environment in China and globally may adversely affect our intellectual property protection. We may face competition for any approved pipeline products even if we successfully obtain patent protection once the patent life has expired for the product. Upon the expiration or invalidation of our issued patents or if our pending patents applications are denied, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Claims that our pipeline products or the sale or use of our products infringe the patents or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to market and sell our commercialized products and to develop and commercialize our pipeline products without infringing, misappropriating or otherwise violating the intellectual property rights of others. We cannot guarantee that our commercialized products and pipeline products 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 commercialized products and pipeline products. 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.

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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.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a marketed product, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement, including treble damages and attorneys’ fees if we are found to willfully infringe a third party’s patent.

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 to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain pipeline products.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing certain pipeline products. Prohibitions against using certain technologies, or prohibitions against commercializing certain pipeline products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. Further, not all of our licensors have represented and warranted under the licensing agreements that our use of in-licensed technologies in connection with the development, manufacture or commercialization of our products or pipeline products will not infringe upon intellectual property rights owned by third parties, or have agreed to indemnify, defend or hold us harmless against any intellectual property infringement claims asserted by third parties.

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There is inevitable uncertainty in any litigation, including intellectual property litigation. There can be no assurance that we would prevail in any intellectual property litigation, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the intellectual property owner in order to continue our research and development programs or to market any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. Alternatively, we may be required to modify or redesign our pipeline products in order to avoid infringing or otherwise violating third-party intellectual property rights. This may not be technically or commercially feasible, may render our pipeline products less competitive, or may delay or prevent the entry of our future approved products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more pipeline products, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our pipeline products to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the [REDACTED].

We or our licensors may be involved in lawsuits to protect or enforce our intellectual property or our licensors' intellectual property, which could lead our patent rights or other intellectual property to be found invalid or unenforceable.

Third parties such as competitors may infringe, misappropriate or otherwise violate our or our licensors' intellectual property rights. Litigation may be necessary to enforce or defend our or our licensors' intellectual property rights. We or our licensors may not prevail in any lawsuits that we initiate, the damages or other remedies award, if any, may not be commercially meaningful, or a court may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' intellectual property rights do not cover the technology in question. Accordingly, our or our licensors' efforts to enforce the intellectual property rights may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, the third parties in such infringement, misappropriation or other intellectual property related actions may challenge the validity and enforceability of our or our licensors' intellectual property rights such as patents, and a court may decide that one or more of our or

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our licensors’ intellectual property rights such as patents are not valid or unenforceable. For example, one of our licensors, Amarin, asserted several U.S. patents against some generic companies, who sought the FDA’s approval for generic products of Vascepa in the U.S. In a court decision handed down by the District Court of Nevada of the U.S. in March 2020, certain claims in the asserted patents were determined to be invalid, which decision was upheld in the appeals by the U.S. Courts for the Federal Circuit on September 3, 2020. The U.S. patents for which certain claims were declared invalid do not have any corresponding Chinese patents or patent applications. It is also unlikely that the invalidation of these U.S. patent claims will have a direct impact on the validity of Chinese patents or patent applications in relation to Vascepa, because the Chinese patents or patent applications in relation to Vascepa are directed to inventions different from those that were declared invalid in the U.S. patents.

Third parties may also raise similar claims of challenges to the validity or enforceability of our or our licensors’ patents before administrative bodies in China or in a foreign country, even outside the context of infringement litigation. Such mechanisms include re-examination, invalidation, *inter partes* review, post-grant review, and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our or our licensors’ patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel, and patent examiners were unaware during prosecution. If a defendant or another party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates, leaving our technology or product candidates without patent protection, and allowing third parties to commercialize our or our licensors’ technology or product candidates and compete directly with us, without payment to us. Even if a defendant or another party does not prevail on a legal assertion of invalidity or unenforceability, our or our licensors’ patent claims may be construed in a manner that would limit our or our licensors’ ability to enforce such claims against the defendant or another party and others. Moreover, if the breadth or strength of protection provided by our or our licensors’ patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our product candidates.

We may be subject to claims asserting that our employees, consultants, independent contractors and advisers have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisers do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims.

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

In addition, while we require our employees 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Changes in intellectual property laws could diminish the value of intellectual property rights in general, thereby impairing our ability to protect our products and pipeline products.

Future changes in laws and regulations governing intellectual property rights and relevant procedures through which patents may be obtained and by which the validity of patents may be challenged could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights. Future changes in laws surrounding patent eligibility may narrow the scope of patent protection available in certain circumstances and weaken our rights as a patent owner in certain situations.

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

Periodic maintenance fees, renewal fees, annual fees and various other governmental fees on intellectual properties such as patents and patent applications are due to be paid to the relevant governmental agencies and other patent agencies in several stages over the lifetime of the intellectual property right. For example, the National Intellectual Property Administration of the PRC or World Intellectual Property Organization and various patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors and patent owners of our in-licensed patent rights to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property. 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.

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Risks Relating to Our Financial Position and Business Operations

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

Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive pharmaceutical market, effective coordination and integration of our businesses and teams, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, increased marketing and customer support activities, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

Our historical operating results may not be representative of future performance.

Our revenue was RMB1,767.8 million, RMB2,073.4 million and RMB2,073.8 million for the years ended December 31, 2020, 2021 and 2022, respectively. We recorded net profit of RMB86.9 million, RMB157.0 million and RMB306.3 million for the years ended December 31, 2020, 2021 and 2022, respectively. During the Track Record Period, our revenue was mainly generated from sales of our core commercialized products, and to a lesser extent, other commercialized products in our portfolio, which may change from time to time. Any change in our product portfolio, such as any acquisition or in-licensing of new products and any termination of existing product sales, may significantly affect our operational results. For example, the exclusive marketing and distribution agreements for Fortum and Zinacef will expire in December 2023.

In addition, we cannot assure you that our historical operating results, such as our revenue, gross profit, net profit, gross profit margin and net profit margin, will be indicative of future performance, for various reasons, including uncertainties of the success of our existing and new pipeline products, and uncertainties of the market and the regulatory environment, our ability to expand production capacity and improve manufacturing capabilities as planned, our ability to manage our distribution network, as well as the intensified competition in the pharmaceutical market in China. Moreover, we recorded certain non-recurring items during the Track Record Period. For example, we recorded a gain on settlement with a terminated distributor of RMB29.2 million for the year ended December 31, 2020, which represented a reversal of provision for certain sales rebates upon expiration of the distribution agreement as we decided to change from one importer to another for Vancocin and FPN starting June 2020 and therefore did not renew the distribution agreement with a major importer. We had provisioned for sales rebates based on historical settlement practice with that distributor. Upon the smooth transition, the distributor did not claim additional sales rebates, and therefore we reversed the specific sales rebates accordingly. For the year ended December 31, 2021, we also recorded a gain on settlement with a terminated distributor of RMB15.6 million, which primarily represented the derecognition of liabilities arising from our historical collaboration with a distributor of Ceclor that no longer need to be paid according to the agreement between us and such distributor, primarily as a result of our acquisition of the Ceclor manufacturing

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facility which allows us to act as the drug manufacturer and distribute Ceclor directly to regional distributors. We recorded other non-recurring gains as well, such as positive net foreign exchange differences and compensation gains. For details, see “Financial Information—Description of Certain Consolidated Statements of Profit or Loss and Other Comprehensive Income Items—Other Income and Gains.” Investors should not rely on our historical results as an indication of our future financial or operating performance.

We face risks related to natural disasters, health epidemics and other outbreaks of contagious diseases, which could have a material adverse effect on our business, financial condition and results of operations.

We are vulnerable to natural disasters and other calamities. Fire, floods, typhoons, earthquakes, power loss, telecommunications failures, break-ins, war, riots, terrorist attacks or similar events may adversely affect our product development progress and on-going clinical trials of our pipeline products, as well as manufacturing, marketing and selling of our products. Our business could also be adversely affected by natural disasters or outbreaks of epidemics such as the Severe Acute Respiratory Syndrome, or SARS, the H5N1 avian flu, the human swine flu, also known as Influenza A (H1N1), or COVID-19. Any of these natural disasters, outbreaks of contagious diseases, or other adverse public health developments in China or any other market in which we operate and conduct business could severely disrupt our business operations by damaging our network infrastructure or information technology system or impacting the productivity of our workforce. Outbreaks of any epidemics in China, especially in the cities where we have operations, may result in material disruptions to the manufacture and delivery of our pharmaceutical products, which in turn may adversely affect our financial condition and results of operations. During the Track Record Period, the progress of our core pipeline products was temporarily delayed due to the global COVID-19 pandemic. However, such delay did not have material adverse effect on our financial condition or results of operations. Any significant disruption to our sales or other activities may negatively affect our liquidity and access to capital. In addition, the outbreak of communicable diseases on a global scale may affect investment sentiment and result in sporadic volatility in global capital markets. Any material change in the financial markets, the PRC economy or regional economies as a result of these events or developments may also materially and adversely affect our business, financial condition and results of operations.

Our future success depends on our ability to retain our senior management team and other key employees and to attract, train, retain and motivate qualified and highly skilled personnel, and if we lose and are unable to replace their service, our business may be adversely affected.

We are highly dependent on our senior management members to manage our business and operations, on our key research and development personnel to develop new products and technologies, to advance regulatory applications and to enhance our existing products, on our key sales and marketing personnel to conduct our sales, promotion and marketing activities. Their deep industry insights, broad expertise and strong execution capabilities have laid the foundation for our continued success. We do not maintain key person insurance. If we lose the service of any member of management or key personnel, we may not be able to locate suitable

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or qualified replacements in a timely manner, or at all. In particular, Mr. Ni, our founder, chairman and chief executive officer, has been crucial to our development and strategic direction. See “Directors and Senior Management.” Our senior management has entered into employment agreements and confidentiality and non-competition agreements with us. However, if any dispute arises between our senior management and us, we may have to incur substantial costs and expenses in order to enforce such agreements in China or we may be unable to enforce them at all.

We compete for qualified personnel with other pharmaceutical and biotechnology companies, universities and research institutions. The pool of suitable candidates is limited, and we may face challenges in attracting and retaining skilled scientists and other technical personnel. We may not be able to hire and retain sufficient skilled and experienced scientists or other technical personnel at the current level of wages. 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 changes in customer needs and 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 pursue collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships, or other strategic initiatives or arrangements, which may fail to produce anticipated benefits and adversely affect our business.

As part of our business strategy, we continually pursue opportunities of collaboration, in-licensing, joint ventures, strategic alliances, or partnerships that we believe would be complementary to or promote our existing business. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, or other strategic arrangements may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all.

Furthermore, partners, collaborators or other parties to such transactions or arrangements may fail to fully perform their obligations or meet our expectations or cooperate with us satisfactorily for various reasons, including risks or uncertainties related to their business and operations. There may be conflicts or other collaboration failures and inefficiencies between us and the other parties.

Such transactions or arrangements may also require or stand in need of actions, consents, approvals, waivers, participation or involvement of various degrees from third parties, such as regulators, government authorities, creditors, licensors or licensees, related individuals, suppliers, distributors, shareholders, or other stakeholders or interested parties. We may not obtain such required or desired actions, consent, approval, waiver, participation or involvement on a timely basis, on acceptable terms, or at all.

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These collaboration, investments and transactions may also present financial, managerial and operational challenges, including:

- diversion of management attention from managing our existing business;
- difficulty with integrating businesses, operations, personnel, financial and other systems;
- lack of experience in operating in the geographical or product markets of the acquired business; and
- the requirement that we periodically review the value at which we carry our investments and, in the event we determine that the value at which we carry an investment has been impaired, the requirement to record a non-cash impairment charge, which charge could substantially affect our reported earnings in the period of such charge, would negatively impact our financial ratios and could limit our ability to obtain financing in the future.

We face potential liabilities, in particular product liability claims or lawsuits, which could cause us to incur substantial liabilities.

The development and commercialization of pharmaceutical products entail inherent risks of harm to patients and we are therefore exposed to risks associated with product liability claims as a result of developing, manufacturing, marketing and selling pharmaceutical products in the jurisdictions in which our products are marketed and sold. In particular, for all of our core commercialized product, Vancocin, Ceclor and FPN, we are the marketing authorization holders in China, assuming the responsibility for the product quality in the full life cycle of the products. Accordingly, we face more risks in our operations. See “Industry Overview—the Pharmaceutical Market in China—Major Trends of China’s Pharmaceutical Market—Implementation of the MAH System.” Such claims may arise if any of our products are deemed or proven to be unsafe, ineffective, defective or contaminated or if we are alleged to have engaged in practices such as inappropriate, insufficient or improper labeling of products or providing inadequate warnings or insufficient or misleading disclosures of side effects. Although we are currently not aware of any material existing or anticipated product liability claims with respect to our products, there can be no assurances that we will not become subject to product liabilities claims or that we will be able to successfully defend ourselves against any such claims.

If a product liability claim is brought against us, it may, regardless of merit or outcome, result in damage to our reputation, breach of contract with our customers, decreased demand for our products, costly litigation, product recalls, loss of revenue and the inability to commercialize our products. If we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management. Moreover, even the allegation that our products are harmful, whether or not ultimately proven, may adversely affect our reputation and sales volumes.

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We do not carry any product liability insurance which are not mandatory under PRC law. Any product liability insurance may be prohibitively expensive, or may not fully cover our potential liabilities. Any business disruption, litigation or natural disaster might result in substantial costs and diversion of resources. Any product liability insurance for clinical trials, when obtained, may be prohibitively expensive, or may not fully cover our potential liabilities. The inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could have a material and adverse effect on our business and results of operations.

Real or perceived incidents of product contamination, or severe side effects caused by our products could materially and adversely affect our reputation, results of operations and financial conditions, and subject us to regulatory actions and contractual liabilities.

Product safety and quality is critical to our business. Our reputation, results of operations and financial condition could be materially and adversely affected by product contamination and our association with any contamination incidents. In addition, the mere publication of information or speculation asserting that any of our products contains or has contained any contaminants, over which we have no control, could damage our reputation and have a material adverse effect on us, regardless of whether such information or speculation have any factual basis. Our products may also cause undesirable or unintended side effects as a result of a number of factors, many of which are outside our control. These factors include potential side effects not revealed in clinical testing, unusual but severe side effects in isolated cases, defective products not detected by our quality management system or misuse of our products by end-users. Our products may also be perceived to cause severe side effects when a conclusive determination as to the cause of the severe side effects is not obtained or is unobtainable. Further, our products may be perceived to cause severe side effects if other pharmaceutical companies’ products containing the same or similar active pharmaceutical ingredients, raw materials or delivery technologies as our products cause or are perceived to have caused severe side effects, or if one or more regulators, such as NMPA or the FDA, or an international institution, such as the WHO, determine that products containing the same or similar pharmaceutical ingredients as our products could cause or lead to severe side effects. Such incidences may cause negative publicity and have material adverse impact on the industry and therefore affect our business and results of operations. If our products cause, or are perceived to cause, severe side effects, we may face a number of consequences, including, but not limited to:

- injury or death of patients;
- a severe decrease in the demand for, and sales of, the relevant products;
- recall or withdrawal of the relevant products;
- revocation of regulatory approvals for the relevant products or the relevant manufacturing facilities;
- damage to the brand name of our products and our reputation;

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- stricter and more frequent regulatory inspections on us;
- removal of relevant products from any medical insurance catalogs or lists of special medications related to the severe diseases insurance;
- inability to participate in the centralized tender process;
- exposure to lawsuits and regulatory investigation relating to the relevant products that result in liabilities, fines or penalties; and
- breach of contract with our major customers.

Certain restrictive covenants of our loans may restrict our ability to obtain further funding, if we do not have access to sufficient funding, our growth and business prospects may be adversely affected.

Our business operations and our implementation of many aspects of our strategies will require significant funding, including:

- the costs of development and commercialization of our pipeline products;
- the costs to in-license new pipeline products to expand and diversify our product portfolio;
- the expenses for expanding our sales and distribution network;
- the funding required for potential future acquisitions and integration of acquired businesses;
- the funding required for potential acquisition or in-licensing for drug assets;
- the funding required for our manufacturing and supply chain management activities, including the implementation of our manufacturing expansion and upgrade plans and manufacturing technology transfer plans;
- the funding required for repaying our existing loans; and
- costs associated our headcount growth.

We expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources. However, our ability to obtain external financing on commercially reasonable terms will depend on a number of factors, many of which are outside of our control, including the global economic conditions, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. In addition, any material adverse change in our results of operations or financial conditions may lead to increased costs for our future funding activities. If we cannot obtain sufficient external financing on commercially acceptable terms to implement our strategies and business plans as currently contemplated, we could be required to revise our strategies and business plans, which could adversely affect our business prospects.

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We are subject to credit risk and counterparty risk of our customers. Any delays in collecting or failure to collect payments from our customers could adversely affect our financial condition or results of operations.

During the Track Record Period, our customers mainly comprise distributors, which include importers and regional distributors. To a lesser extent, our customer during the Track Record Period also included a limited number of overseas pharmaceutical companies to which we provided promotion services. We require our importer to deliver letters of credit with a term of no more than 180 days at least one week prior to delivery of products. For regional distributors with good credit standing, we generally grant them a short credit term of 30 to 60 days on a case-by-case basis based on our assessment. In addition, even for certain distributors to whom we grant a credit term, we provide certain monetary incentives to encourage them to make spot payment instead. We may be exposed to credit risks. If we experience delays in collecting or if we are unable to collect payments from customers, our cash flows and operations could be adversely affected. We may experience delays or failure to collect payments we expected from certain MNCs to which we provided promotion services, if sales of our customer’s products to distributors were not made due to our customers’ own reasons. We cannot assure you that we can properly assess and respond in a timely manner to changes in their credit profile. If our customers’ cash flows, working capital, financial condition or results of operations deteriorate, they may be unable, or they may otherwise be unwilling, to pay trade receivables owed to us promptly or at all. Any substantial defaults or delays could materially and adversely affect our cash flows, and we could be required to terminate our relationships with our customers in a manner that may adversely and materially affect our cash flows and operations.

We incurred net current liabilities of December 31, 2021 and 2022, and may continue to do so in the future, which can expose us to liquidity risk.

We recorded net current liabilities of RMB675.8 million, RMB930.4 million and RMB306.7 million as of December 31, 2021 and 2022 and April 30, 2023, respectively. We may continue to have net current liabilities in the future. Having significant net current liabilities could constrain our operational flexibility and adversely affect our ability to expand our business. If we are unable to generate sufficient cash flow from our operations to meet our present and future financial needs, we may need to resort to external funding. If adequate external funds are not available on commercially reasonable terms, or at all, we may face liquidity difficulties. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Our indebtedness and the conditions and restrictive covenants imposed on us by our financing agreements could materially and adversely affect our business, financial conditions and results of operations.

As of April 30, 2023, our total bank and other borrowings were RMB2,393.8 million, which consisted of our secured and unsecured bank loans, primarily including a mezzanine loan of US\$105 million, a senior term loan of US\$110 million plus HK\$120 million (with a total credit facility of US\$150 million), as well as certain other loans from banks. See “Financial Information—Indebtedness.” We intend to repay such indebtedness with cash flows from operations and [REDACTED] from the [REDACTED]. However, we may continue to incur debt to fund our daily operations and to pursue our expansion plans. This indebtedness could have important consequences for our business and operations including, but not limited to:

- limiting or impairing our ability to obtain financing, including bridge financing, refinance any of our indebtedness, obtain equity or debt financing on commercially reasonable terms or at all, which could cause us to default on our obligations and materially impair our liquidity;

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- restricting or impeding our ability to access capital markets at attractive rates and increasing the cost of future borrowings;
- reducing our flexibility to respond to changing business and economic conditions or to take advantage of business opportunities that may arise;
- resulting in the assets we provide as collateral for the borrowings under risk of foreclosure;
- requiring us to dedicate a substantial portion of our cash flow from operations to payments of principal and interest on our indebtedness, thereby reducing the availability of our cash flow for other purposes;
- restricting our ability to distribute dividends or make other distributions to Shareholders;
- placing us at a competitive disadvantage compared to our competitors that have lower leverage or better access to capital resources;
- limiting our ability to dispose of assets that secure our indebtedness or utilize the proceeds of such dispositions and, upon an event of default under any such secured indebtedness, allowing the lenders thereunder to foreclose upon our assets pledged as collateral; and
- increasing our vulnerability to downturns in general economic or industry conditions, or in our business.

In addition, our bank loan agreements include various conditions and covenants that require us to obtain the lending bank’s prior consent for certain transactions, such as disposal of material assets, merger or consolidation, liquidation or winding-up, or providing guarantee, mortgage or other forms of security to other borrowings. If we breach these covenants or other similar terms under the agreements, the relevant loans may become repayable on demand or subject to accelerated repayment terms, or may trigger cross-default terms. We have mortgaged our manufacturing facilities in Suzhou and pledged certain trademarks and equity interest in some of our subsidiaries to secure our bank loans. Our production and sales revenue would be materially and adversely affected and we could lose control of relevant trademarks or subsidiaries, if the lenders enforce the collaterals upon an event of default. See “Financial Information—Indebtedness” for more details. Furthermore, we may be required to comply with similar restrictive covenants or other terms under any new loan and other financing agreements in the future.

Should market conditions deteriorate, or if our operating results were to be depressed, we may need to request amendments or waivers to the covenants and restrictions under our debt agreements. A breach of any of these covenants or restrictions could result in a default that would permit our lenders to declare all amounts outstanding thereunder to be due and payable, together with accrued and unpaid interest, trigger cross-default provisions under other debt agreements and, as applicable, cause the termination of commitments of relevant lenders to make further extensions of credit under our financing agreements or credit facilities. There can be no assurance that we will be able to obtain such relief should it be needed. If we were unable to repay our indebtedness to our lenders in such an event, the lenders could, among other things, proceed against collateral, which could include substantially all of our assets. Our future ability to comply with financial covenants and other conditions, make scheduled payments of principal and interest or refinance existing borrowings according to our business performance, which is subject to economic, financial, competitive and other factors, including the other risks described in this document. Any failure to comply with the covenants of our financing agreements or to obtain financing for our business could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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Any goodwill impairment could adversely affect our results of operations and financial condition.

We recorded goodwill of RMB112.1 million, RMB112.1 million and RMB112.1 million as of December 31, 2020, 2021 and 2022, respectively, primarily in connection with our acquisition of Ceclor. Goodwill accounted for 2.1%, 2.3% and 2.2% of our total assets as of December 31, 2020, 2021 and 2022, respectively. We undertake goodwill impairment reviews annually or more frequently if events or changes in circumstances indicate a potential impairment. We compare the carrying value of goodwill to the recoverable amount. We recognize any impairment immediately and it is not subsequently reversed. If the carrying value of our goodwill is considered to exceed its recoverable amount and our goodwill is therefore determined to be impaired in the future, we would be required to write down the carrying value or record a provision of impairment loss for goodwill in our financial statements during the period in which our goodwill is determined to be impaired, and this impairment would adversely affect our results of operations and our financial condition.

We may need to make provision for impairment loss for our other intangible assets, which could negatively affect our results of operations and financial condition.

We record other intangible assets, primarily including exclusive rights of new drugs, software, trademarks and know-how licenses. As of December 31, 2022, the aggregate carrying value of these intangible assets amounted to RMB2,710.7 million, accounting for 53.6% of our total assets as of the same date. Other intangible assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. Intangible assets that are not available for use, such as our know-how license of FPN, are tested for impairment annually. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount. If any of these intangible assets is determined to be impaired in the future, we would be required to write down the carrying value or record a provision of impairment loss for these intangible assets in our financial statements during the period in which the relevant intangible assets were determined to be impaired, and this would negatively affect our results of operations and our financial condition.

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 have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our manufacturing facility may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous materials and wastes. We contract with third parties for the disposal of these materials and wastes, but we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or production of hazardous wastes, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. For details, see “Regulations—Overview of PRC Regulations—Regulations in Relation to Environmental Protection and Safety—Environmental Protection.” In addition, any negative publicity concerning environmental matters in relation to us, even if untrue, could adversely affect our reputation and business prospects.

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Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. In addition, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with environmental, health and safety laws and regulations when we operate our manufacturing facilities. As the requirements imposed by environmental, health and safety laws and regulations may change and more stringent laws or regulations may be adopted and enforcement practices may vary, we may have difficulties complying with, or accurately predicting the potentially substantial cost of complying with, these laws and regulations, which may subject us to rectification orders, substantial fines, monetary damages and suspension or cessation of research activities and other business operations. These laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our internal computer systems, or those used by our CROs or partners or other contractors or consultants, may fail or suffer security breaches or other disruptions.

Our internal computer systems and those of our CROs, partners and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. We, our CROs, partners and other contractors and consultants rely on various information technology systems and software applications to manage many aspects of business, including product manufacturing and development, management of our supply chain, sale and delivery of our products, financial reporting and various other processes and transactions. We, our CROs, partners and other contractors and consultants are critically dependent on the integrity, security and consistent operations of these systems and related back-up systems. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. Information systems, networks and other technologies are critical to our operating activities, shutdowns or service disruptions at our offices or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events, such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have an adverse impact on us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our

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operations, damage to our reputation or a loss of revenues. We could be subject to regulatory actions and/or claims 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. In addition, as we outsource more of our information systems to vendors 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.

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

The cost of labor in the PRC has been steadily increasing over the past years as a result of inflation, government-mandated wage increases and other changes in PRC labor laws, as well as competition for talents and qualified employees among pharmaceutical companies. Unless we are able to pass on these increased labor costs to our customers by increasing the prices of our products, our financial condition and results of operations may be adversely affected. Many aspects of our strategies and business growth may require us to have additional employees. We may also have additional employees as a result of acquisitions or organic growth of our business. If we implement such strategies but fail to realize the benefits and efficiencies we anticipate, we may be unable to offset the corresponding increases in our staff costs, which adversely affect our revenues and profitability.

Failure to pay the social insurance and housing provident funds for and on behalf of our employees in accordance with the Labor Contract Law or comply with other PRC regulations may have an adverse impact on our financial conditions and results of operation.

PRC companies are required to pay for their employees’ social insurance (including pension insurance, unemployment insurance, medical insurance, work-related injury insurance and maternity insurance) and housing provident funds in amounts equal to certain percentage of salaries, including bonuses and allowances, of their employees up to a maximum amount specified by the local government from time to time at locations where they operate their business.

According the applicable PRC laws and regulations, an employer shall open social insurance registration account and housing provident funds account and pay social insurance and housing provident funds for its employees. During the Track Record Period, some of our subsidiaries engaged a third-party human resources agency to pay social insurance and housing provident funds for a fair of their employees. As of the Latest Practicable Date, the human resources agency paid insurance premium, including basic pension insurance, basic medical insurance, work injury insurance, unemployment insurance, and maternity insurance, and housing provident funds, and none of these subsidiaries had received any administrative penalty or labor arbitration application from employees for its agency arrangement with the third-party human resources agency. We may be subject to penalties imposed by the local social insurance authorities and the local housing provident fund management centers for failing to make payment of social insurance and housing provident funds for the employees in the employer’s own name.

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

From time to time, we may be involved in claims, disputes and legal proceedings in our ordinary course of business. Any claims, disputes and legal proceedings may concern issues relating to, among others, product liability, environmental matters, breach of contract, employment or labor disputes and infringement of intellectual property rights. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us or our Directors which may have a material adverse impact on our business, financial condition or results of operations. Any claims, disputes or legal proceedings initiated by us or brought against us, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. See “Business—Legal Proceedings and Regulatory Compliance.” Furthermore, claims, disputes or legal proceedings against us may be due to defective supplies sold to us by our suppliers, who may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

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

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or product liability insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Negative publicity may adversely affect our reputation, business and growth prospect.

Any negative publicity concerning us, our affiliates, any entity that shares our brands or MNCs we cooperate with, and the pharmaceutical industry in China in general, even if untrue, could adversely affect our reputation and business prospects. We cannot assure you that negative publicity about us, any of our affiliates, any entity that shares our brands or MNCs we cooperate with would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition. In addition, referrals have significantly contributed to our ability to establishing new partnerships. As a result, any negative publicity about us, any of our affiliates, any entity that shares our brand name or MNCs we cooperate with could adversely affect our ability to maintain our existing collaboration arrangements or attract new partners.

We are subject to risks associated with leasing property.

We lease some of our offices and manufacturing sites in China. The lessors of the leased properties 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.

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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 had not filed ten 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 RMB100,000 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.

If we fail to comply with applicable anti-bribery and anti-corruption laws and regulations, 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 and anti-corruption laws and regulations. Our business activities create the risks of unauthorized payments or offers of payments by our employees. We implement strict internal control and risk management procedures to discourage these practices. Our distributors are subject to an anti-corruption and anti-bribery obligation pursuant to our distribution agreements, under which distributors are obligated to ensure themselves and their associates and their sub-distributors and the associates of the sub-distributors to be in full compliance with the Compliance Code (合規標準), the Anti-Misconduct Policy (反舞弊政策), the Operating Expense Management Manual (運營費用管理手冊), Business Ethics Policy (商業道德政策), the Staff Book (員工手冊), Guidelines for Engagement with Governmental Officials (與政府官員交往指南) and Policy on Promotion and Non-Promotion Materials (推廣材料和非推廣材料的管理規定). We periodically provide anti-corruption compliance training to our Directors and employees to enhance their compliance awareness with applicable laws and regulations. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees and distributors may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities. Noncompliance with anti-corruption laws could subject us investigations, enforcement actions, fines, or civil or criminal penalties.

We do not and cannot fully control the conduct of our employees, agents, distributors or suppliers or affiliates. Our employees, agents or distributors may, in their interactions with hospitals, medical institutions and medical professionals, attempt to increase the sales volume of our products through means that constitute violations of applicable anti-corruption and other related laws. If our employees, agents, or distributors engage in corrupt or other improper conduct that result in violation of applicable anti-corruption laws in respective jurisdictions, our reputation could be harmed. While we have implemented specific measures against corruption and bribery, there can be no assurance that we were or are able to entirely prevent our employees or distributors from engaging in such activities in the past or in the future. We may be held liable for actions taken by our employees or distributors, which could expose us

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to regulatory investigations and penalties. Actions taken by relevant regulatory authorities or courts that provide an interpretation of laws and regulations that differs from our interpretation or that adopt additional anti-bribery, anti-corruption laws and regulations could also require us to make changes to our operations. Our reputation, corporate image, and business operations may be materially and adversely affected if we, our employees, distributors or suppliers fail to comply with these measures or become the target of any negative publicity as a result of actions taken by us, our employees, distributors or affiliates, which may in turn have a material adverse effect on our results of operations and prospects.

For example, pursuant to the Regulations on the Establishment of Bad Records with respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the NHFPC and came into effect on March 1, 2014, if we have conducted a crime of bribery as determined by the ruling of a people’s court (regardless of the exemption of criminal punishment), or we are involved in an investigation for commercial bribery and punishment is imposed, or we have been imposed administrative penalties by SAMR, NMPA or other governmental authorities, we will be listed in the adverse records of commercial briberies by the relevant government authorities, as a result of which our products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant province for two years from the date on which such adverse records are published. If we are listed in the adverse records of commercial briberies twice within five years, our products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies throughout China for two years. As of the Latest Practicable Date, we were not listed in any adverse records of commercial briberies.

After the credit assessment system of the price of drugs, and bidding and procurement (醫藥價格和招採信用評價制度) is officially established, if we have conducted offering rebates or other unlawful benefits in sale of drugs, abuse of market dominant position, violation in tax laws, improper price competition, malicious breach of contracts, disturbing the order of centralized drug procurement, we may be listed as one of the discredited enterprises, and may further be subject to suspension of bidding qualification or suspension of distribution of the winning drug, which will adversely affect our bidding in centralized drug procurement.

We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees, suppliers or other third parties, including corrupt practices, inappropriate promotion of our products or the third-party products that we sell and/or promote, or leakage of confidential information.

We may be exposed to fraud, bribery or other misconduct committed by our employees, distributors, sub-distributors, customers, suppliers or other parties we cooperate with in China or other jurisdictions. Any actual or alleged wrongdoing or misconduct, over which we may not have full control, could subject us to regulatory investigation, liabilities, financial losses, sanctions imposed by governmental authorities and negative publicity, which may adversely affect our reputation and prospects. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees or other third parties that had any material and adverse impact on our business and results of operations. However, we do not and cannot fully control the conduct of our employees, distributors, sub-distributors, suppliers or affiliates, and we cannot assure

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you that there will not be any such instances in the future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

If our risk management and internal control system is not adequate or effective, and if it fails to detect potential risks in our business as intended, our business, financial condition and results of operations could be materially and adversely affected.

We have an internal control system in place to monitor and control potential risk areas relevant to our business operations. In connection with the [REDACTED], we have examined our internal control system and made certain enhancements where appropriate, in order to satisfy our internal control requirements after the completion of the [REDACTED]. However, due to the inherent limitations in the design and implementation of our internal control system, our internal control system may not be sufficiently effective in identifying, managing and preventing all risks if external circumstances change substantially or extraordinary events take place.

Further, integration of various business operations from potential future acquisitions may give rise to additional internal control risks that are currently unknown to us, despite our efforts to anticipate such issues. If our internal control system fails to detect potential risks in our business as intended, or is otherwise exposed to weaknesses and deficiencies, our business, financial condition and results of operations could be materially and adversely affected.

Our risk management and internal controls also depend on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct. If we fail to implement our policies and procedures in a timely manner, or fail to identify risks that affect our business with sufficient time to plan for contingencies for such events, our business, financial condition and results of operations could be materially and adversely affected, particularly with respect to the maintenance of our relevant approvals and licenses granted by the relevant authorities.

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

We recognized RMB5.9 million, RMB4.0 million and RMB1.5 million of government grant income for the years ended December 31, 2020, 2021 and 2022, respectively. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate government grants to us at any time. We cannot assure you of the continued availability of the government grants currently enjoyed by us. Any reduction or elimination of government grants would have an adverse effect on our results of operations.

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Fluctuations in exchange rates may result in foreign currency exchange losses and may have a material adverse effect on our profitability.

We are exposed to exchange rate risks related to other currency that can affect our revenue, costs, margins and profits. We recorded net foreign exchange gains of RMB60.6 million and RMB13.9 million in 2020 and 2021, respectively. We recorded net foreign exchange losses of RMB3.1 million in 2022. We also recorded exchange differences on translation of foreign operations of RMB(138.6) million, RMB(40.5) million and RMB95.9 million, in 2020, 2021 and 2022, respectively, which represented the exchange differences of translating foreign functional currencies of foreign subsidiaries into Renminbi for the purposes of preparing our audited financial statements. An increase in the value of the US dollar or EUR or other foreign currencies against the Renminbi may have a material adverse effect on our profitability. When managing our exposure to currency risk, we may use foreign currency forward contracts and other strategies to mitigate currency risk and there can be no assurances that these strategies will be successful.

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

Our Company granted certain options under the 2020 Share Option Scheme, details and principal terms of which are set forth in “Appendix IV—Statutory and General Information—D. Share Incentive Plan—1. 2020 Share Option Scheme.” For further details, see note 32 to the Accountants’ Report in Appendix I to this document. In 2020 and 2021, we incurred equity-settled share-based payment expenses of RMB42.8 million and RMB46.3 million, respectively. In 2022, we reversed equity-settled share-based payment expenses of RMB39.6 million. To further incentivize our employees, we may grant additional share-based incentives in the future. Issuance of additional Shares with respect to such share-based incentives may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based incentives may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

RISKS RELATING TO CONDUCTING BUSINESS IN THE PRC

Changes in the political and economic policies of the PRC government may affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

During the Track Record Period, substantially all of our business operation were located in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by changes in government grants granted or currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These

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measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

The PRC legal system is evolving and could limit the legal protection available to you.

Our business is conducted in China and is governed by PRC laws and regulations. Our business operation is supervised by competent regulatory authorities in China. The PRC legal system is based on written statutes and prior court decisions can only be cited as reference, which have limited precedential value. Additionally, written statutes in the PRC are often principle-oriented and require detailed interpretations by the enforcement bodies to further apply and enforce such laws. The interpretation and enforcement of PRC laws, rules and regulations involve certain uncertainties. As these laws and regulations are continually evolving in response to changing economic and other conditions, and because of the limited volume of court decisions and their non-binding nature, any particular interpretation of PRC laws and regulations may not be definitive. Moreover, we cannot predict the effect of future developments in the PRC legal system and regulatory structure. Such unpredictability towards our contractual, property and procedural rights as well as any changes to our rights licensed, approved or granted by the competent regulatory authority could adversely affect our business and impede our ability to continue our operations.

Uncertainties exist with respect to the interpretation and implementation of the PRC Foreign Investment Law, which may impose new burdens on us.

The PRC Foreign Investment Law, or the FIL, was enacted by the NPC on March 15, 2019 and became effective on January 1, 2020, which replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. This law has become the legal foundation for foreign investment in the PRC. The FIL embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, uncertainties exist with respect to interpretation and implementation of the FIL and its Implementation Rules, which may adversely impact our corporate governance practice and increase our compliance costs. For instance, we might be required by government interpretations or implementing rules of the FIL to adjust the corporate governance of certain of our PRC subsidiaries in a five-year transition period. In addition, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

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Geopolitical tensions may affect our business operations.

During the Track Record Period, we relied on certain overseas CMOs and suppliers to manufacture and supply APIs and raw materials for our products and pipeline products, and we have relied on the services, such as logistics services, from and collaboration with entities in foreign countries and regions. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. Tensions and political concerns between China and the relevant foreign countries or regions or in between the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects.

China’s political relationships with relevant foreign countries and regions where our overseas collaborators are based may affect the prospects of our relationship with third parties. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions.

Furthermore, in the event that China and/or any relevant foreign countries and regions impose higher tariffs, trade restrictions or other trade barriers affecting our importation of components or raw materials or other import and export activities, we may not be able to obtain a steady supply of necessary components or raw materials or any other necessary supplies at competitive prices, and our business and operations may be materially and adversely affected.

We may be subject to the approval or other requirements of the CSRC or other PRC government authorities in connection with future capital raising activities.

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Overseas Listing Trial Measures”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities. Any such domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

As advised by our PRC Legal Advisers, we are required to go through the filing procedures with the CSRC under the Overseas Listing Trial Measures. We will file with the CSRC within the specific time limit as required by the Overseas Listing Trial Measures and seek guidance from the relevant regulator and/or our legal advisers to ensure our compliance in all respects. Given that the Overseas Listing Trial Measures and its relevant supporting guidelines were recently promulgated, there remain substantial uncertainties as to their interpretation, application, and enforcement and how they will affect our operations and our future financing. In addition, it is uncertain whether we can or how long it will take us to

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complete such filings. Any failure to complete such filings may impede the [REDACTED] and may subject us to sanctions by the CSRC or other PRC government authorities. Furthermore, such failure may adversely affect our ability to finance the development of our business and may have a material adverse effect on our business and financial condition.

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

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, unless the aggregate amount of such fund has reached 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

In recent years, the PBOC and the SAFE promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

Our dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than what we currently anticipate.

The EIT Law and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are Non-PRC Resident Enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor’s jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement.

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Pursuant to the Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of the PRC-sourced income and we have obtained the approval of the competent tax authority. On February 3, 2018, the STA issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (《關於稅收協定中“受益所有人”有關問題的公告》), also known as Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent or a designated payee will not be regarded as a beneficial owner.

If our Hong Kong subsidiary holds any equity interest in a PRC subsidiary and does not engage in any substantive business activity in the future, based on the abovementioned principles, PRC tax authorities would not treat our Hong Kong subsidiary as the “beneficial owner” of any dividends paid from our PRC subsidiaries and would deny the claim for the application of the reduced rate of withholding tax. Under the current PRC tax law, if our Hong Kong subsidiary is not treated as a “beneficial owner,” dividends from our PRC subsidiaries to our Hong Kong subsidiary being subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and our ability to pay dividends in the future.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. All of our revenue is denominated in Renminbi and will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments to holders of our Shares, or otherwise satisfy their foreign currency denominated obligations. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, trade and service-related foreign exchange transactions without the approval of SAFE by complying with certain procedural requirements. However, for transactions under the “current account”, such as foreign direct investment and foreign currency debt, including loans we may secure for our PRC subsidiaries, approvals from, or registration with, SAFE and other relevant PRC governmental authorities are required, which may limit our ability to obtain foreign currency through debt or equity financing for our PRC subsidiaries. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in Renminbi to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares.

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Future changes in laws, regulations or enforcement policies in China could adversely affect our business.

Laws, regulations or enforcement policies in China, including those regulating healthcare and the pharmaceutical industry, are evolving. Currently, the PRC pharmaceutical industry is heavily regulated and many aspects of our business depend on the receipt of the relevant government authorities’ approvals and permits. Further, enforcement practices of regulatory agencies in China are evolving and we face uncertainties in predicting such changes. Therefore, prior enforcement activity, or lack of enforcement activity, is not necessarily predictive of future actions. Any enforcement actions against us could have a material adverse effect on us. Any litigation or governmental investigation or enforcement proceedings in China may be lengthy and may result in substantial costs and diversion of resources and management attention, negative publicity, and damage to reputation. In addition, such changes may be applied retroactively and thus subject our business and operations to increased uncertainties and risks.

For example, since late 2015, the PRC regulatory authority has promulgated a series of regulations setting forth the requirements of consistency evaluation for generic drugs, including the Opinions of the General Office of the State Council on Conducting the Quality and Efficacy Conformity Evaluation for Generic Drugs (《國務院辦公廳關於開展仿製藥質量 and 療效一致性評價的意見》), the Announcement on Relevant Matters Concerning the Quality and Efficacy Conformity Evaluation for Generic Drugs (No. 100 (2017)) (《關於仿製藥質量 and 療效一致性評價工作有關事項的公告》) and the Announcement on the Relevant Matters Concerning the Quality and Efficacy Conformity Evaluation for Generic Drugs (No. 102 (2018)) (《關於仿製藥質量 and 療效一致性評價有關事項的公告》), which set forth timelines for completion of conformity evaluation and consequences for failure to timely complete the evaluation. Our future drug applications are now subject to stricter evaluation standard. If we are unable to fulfill the requirements of the evolving laws and regulations, our business operation may be adversely affected.

It may be difficult to effect service of process upon us or our management that reside in China or to enforce against them or us in China any judgments obtained from foreign courts.

Substantially all of our Directors and management personnel reside in China and substantially all of assets of our Directors and management personnel are located within China. Therefore, it may not be possible for investors to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of many other jurisdictions.

On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money

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in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. On January 18, 2019, the Supreme People’s Court and the Hong Kong Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court and the completion of the relevant legislative procedures in the Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

Furthermore, China does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the United States, the United Kingdom, most other western countries or Japan. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

Any failure by the Shareholders or beneficial owners of our Shares to comply with certain PRC foreign exchange regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.

The SAFE has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities, including SAFE Circular 37. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result

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in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (i) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive and (ii) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (《國家外匯管理局關於發佈境內機構境外直接投資外匯管理規定的通知》), or SAFE Circular 30, and other regulations, if our Shareholders who are PRC entities do not complete their registration with the competent SAFE, NDRC or MOFCOM branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our Shareholders may be required to suspend or stop the investments and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restriction.

Pursuant to the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), or SAFE Circular 13, local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of SAFE.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying with and procuring that our Shareholders who are subject to the regulations comply with the relevant SAFE rules and regulations. However, due to the uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not always be practically available in all circumstances as prescribed in those regulations. In addition, we may not always be fully aware or informed of the identities of our beneficiaries who are PRC nationals or entities, and may not be able to compel them to comply with SAFE Circular 37, SAFE Circular 30 or other related regulations. We cannot assure you that the SAFE or its local branches will not release explicit requirements or interpret the relevant PRC laws and regulations otherwise. Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

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We face uncertainty relating to transfers by a non-resident enterprise of assets of a PRC resident enterprise.

On February 3, 2015, the STA issued the Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》), or Circular 7, which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on non-Resident Enterprises (《關於加強非居民企業股權轉讓企業所得稅管理的通知》), or Circular 698, which was previously issued by the STA on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 provides comprehensive guidelines relating to, and heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or PRC Taxable Assets. STA issued the Circular on the Source of Deduction of Income Tax for Non-resident Enterprises (《國家稅務總局關於非居民企業所得稅源泉扣繳有關問題的公告》, “Circular 37”) on October 17, 2017, as later amended on June 15, 2018, which further clarifies the practice and procedure of withholding EIT from or payment of EIT by a non-resident enterprise in such circumstances and defines how the capital gain of a non-resident enterprise should be calculated.

Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market,” or the Public Market Safe Harbor, which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in “Information about this Document and the [REDACTED] in this document, potential investors should consult their professional advisers if they are in any doubt as to the tax implications of [REDACTED], purchasing, holding, disposing of and dealing in the Shares.

We may be classified as a “resident enterprise” under EIT Law, which may subject us and our non-PRC shareholders to unfavorable tax consequences.

Under the EIT Law, an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it will be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. Under the Circular of the STA on Issues Concerning the Identification of Chinese-Controlled Enterprises Registered Overseas as Resident Enterprises on the Basis of Their De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) issued by the STA on April 22, 2009, or Circular 82, dividends and other distributions paid by resident enterprises will be considered to be PRC source income, subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by Non-PRC Resident Enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting,

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and properties” of the enterprise. In addition, Circular 82 specifies that certain China-invested enterprises will be classified as resident enterprises. On July 27, 2011, the STA issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資控股居民企業所得稅管理辦法(試行)》), or Bulletin 45, which became effective on September 1, 2011 and as amended in 2015, 2016 and 2018, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which the competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Despite the foregoing, the STA may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by PRC enterprise would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by PRC enterprise like us. Finally, the EIT Law and its implementing rules issued by PRC tax authorities provide that dividends paid by us to our non-PRC shareholders and, while less clear, capital gains recognized by them with respect to the sale of our Shares may be subject to tax of 10% for Non-PRC Resident Enterprise shareholders and 20% for non-PRC resident individual shareholders. In the case of dividend payments, such PRC tax may be withheld at source.

Anti-monopoly and unfair competition claims or regulatory actions against us may result in our being subject to fines, constraints on our business and damage to our reputation.

The PRC anti-monopoly enforcement agencies have recently strengthened enforcement under the PRC Anti-monopoly Law. In March 2018, the SAMR was formed as a new governmental agency to take over, among other things, the anti-monopoly enforcement functions from the relevant departments under the MOFCOM, the NDRC and the SAIC, respectively. Since its inception, the SAMR has continued to strengthen its anti-monopoly enforcement, including the issuance of the “Notice of State Administration for Market Regulation on Anti-monopoly Enforcement Authorization” (《市場監管總局關於反壟斷執法授權的通知》) on December 28, 2018, which grants authorizations to the branches of SAMR at the provincial level for anti-monopoly enforcement within their respective jurisdictions. On June 26, 2019, the SAMR promulgated the “Interim Provisions on Prohibiting Monopoly Agreement” (《禁止壟斷協議暫行規定》) and the “Interim Provisions on Prohibiting Abuse of

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Dominant Market Positions” (《禁止濫用市場支配地位行為暫行規定》) (collectively, the “Interim Provisions”), which became effective on September 1, 2019. Pursuant to the PRC Anti-monopoly Law and the Interim Provisions, companies are prohibited from reaching monopoly agreements on price of products with their counterparties, including directly or indirectly fixing resale price of products or limiting bottom resale price of products; companies are also prohibited from conducting abusive behaviors leveraging their market dominance, including selling products at unfairly high prices and directly or indirectly refusing to transact with specific counterparties without justification. The relevant anti-monopoly laws also provide a private right of action for competitors, business partners or customers who suffered losses caused by monopolistic behaviors to bring anti-monopoly claims. In recent years, an increasing number of companies have been exercising their right to seek relief under the PRC Anti-monopoly Law.

Recently, the SAMR pays close attention to potential monopolistic business practices in the pharmaceutical industry. In particular, it has conducted anti-monopoly investigations on, and imposed administrative penalties on, various companies in the pharmaceutical industry for their abusive behavior leveraging their market dominance. Consequently, we may be perceived to have dominance in such markets. During our normal course of business, we may adjust the supply price of such products, make decisions on whether to transact with specific counterparties, establish business relationships with additional counterparties or terminate business relationships with existing counterparties at our sole discretion.

Although we believe that our business practices are conducted based on commercially reasonable considerations and justifications and do not violate the PRC Anti-monopoly Law or the Interim Provisions, there can be no assurance that other companies, including our competitors, business partners and customers, will submit complaints to regulators or initiate private litigation that targets our prior and current business practices, nor can we assure you that regulators will not initiate anti-monopoly investigations into specific business practices we have adopted. Any anti-monopoly lawsuit, regulatory investigations or administrative proceedings initiated against us, regardless of their merits, could materially and adversely harm our business and reputation. If we are perceived to violate anti-monopoly laws, regulations or policies in the PRC, we will be exposed to penalties, confiscation of illegal gains and cease of illegal business practices, which could materially and adversely affect our business, results of operations and financial condition.

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

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of SAFE. Additionally, if we finance such subsidiary by means of additional capital contributions, these capital contributions must be registered, reported or filed with certain government authorities, including the MOFCOM or its local counterparts and SAMR through the Enterprise Registration System (企業登記系統) and the National Enterprise Credit Information Publicity System (國家企業信用信息公示系統) and SAFE. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our

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subsidiaries or any of their respective subsidiaries. If we fail to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries’ liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments. As a result, this may have a material adverse effect on our business, financial condition and results of operations.

Any failure to comply with the PRC regulations regarding our employee equity incentive plans may subject PRC plan participants or us to fines and other legal or administrative sanctions.

On February 15, 2012, SAFE issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly-Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the Share Option Rules. Under the Share Option Rules, PRC citizens or residents habitually residing in the PRC continuously for over one year, with a few exceptions, and who have been granted, restricted shares or share options by an overseas listed company according to its employee share option or share incentive plan, are required to appoint a qualified PRC agent, register with SAFE or its local counterparts, and complete certain other procedures related to the shareholding plan, share option plan or other similar share incentive plans. Such participants must also retain an overseas entrusted institution to handle matters in connection with their exercise of stock options, the purchase and sale of corresponding stocks or interests and fund transfers. In addition, the PRC agents are required to amend or deregister the registrations with SAFE or its local counterparts in case of any material change in, or termination of, the share incentive plans within the time periods provided by the Share Option Rules.

We and our PRC resident employees who have been granted share options will be subject to the Stock Option Rules upon completion of this [REDACTED]. Failure of the PRC resident holders of our share options to complete their SAFE registrations may subject these PRC residents to fines and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, limited our PRC subsidiaries’ ability to distribute dividends to us, or otherwise materially adversely affect our business.

The STA has also issued relevant rules and regulations concerning employee share incentives. Under these rules and regulations, our employees working in the PRC will be subject to PRC individual income tax upon exercise of the share options. Our PRC subsidiary has obligations to file documents with respect to the granted share options or restricted shares with relevant tax authorities and to withhold individual income taxes for their employees upon exercise of the share options or grant of the restricted shares. If our employees fail to pay or if we fail to withhold their individual income taxes according to relevant rules and regulations, we may face sanctions imposed by the competent governmental authorities.

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RISKS RELATING TO THE [REDACTED]

An active [REDACTED] for our Shares may not develop and the [REDACTED] for our Shares may decline or become volatile.

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

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

The [REDACTED] and [REDACTED] volume of our 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 market price of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] volume of our Shares. In addition to market and industry factors, the [REDACTED] and [REDACTED] volume of our Shares may be highly volatile for various business reasons, such as actual or anticipated fluctuations in our revenue and operating results, the results of clinical trials of our pipeline products, the results of our applications for approval of our pipeline products, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, relationships with our customers, suppliers and distributors, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in [REDACTED] not directly related to our performance.

Our Controlling Shareholders have substantial influence over our Company and their interests may not be aligned with the interests of other Shareholders.

Immediately following the completion of the [REDACTED] and without taking into account any exercise of the [REDACTED] and any shares to be issued upon the exercise of the options under the 2020 Share Option Scheme, our Controlling Shareholders will be entitled to exercise voting rights of [REDACTED]% of the total issued share capital of our Company. The interests of our Controlling Shareholders may differ from the interests of our other Shareholders. Our Controlling Shareholders could have significant influence in determining our business and affairs, including the terms and outcome of any corporate transaction (such as acquisition or disposition of assets, issuance of additional shares or other equity securities, and timing and amount of dividend payments), our management and other matters submitted

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to our Shareholders for approval. This concentration of ownership, as a result, may discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for their Shares in a sale of our Company or may reduce the [REDACTED] of our Shares. In addition, to the extent the interests of our Controlling Shareholders conflict with the interest of our other Shareholders, the interests of our other Shareholders may be disadvantaged or harmed.

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

The initial [REDACTED] to the public of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be five Business Days after the [REDACTED]. As a result, investors may not be able to sell or otherwise [REDACTED] the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the [REDACTED] of the Shares when trading 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 sale and the time [REDACTED] begins.

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

Sales of substantial amounts of Shares in the public market after the completion of the [REDACTED], or the perception that these sales could occur, could adversely affect the [REDACTED] of our Shares. Although our Controlling Shareholders are subject to restrictions on its sales of Shares within 12 months from the [REDACTED] as described in “[REDACTED]” in this document, future sales of a significant number of our Shares by our Controlling Shareholders in the public market after the [REDACTED], as a result of a share pledge or otherwise, or the perception that these sales could occur, could cause the [REDACTED] of our Shares to decline and could materially impair our future ability to raise capital through [REDACTED] of our Shares. We cannot assure you that our Controlling Shareholders will not dispose of Shares held by them or that we will not issue Shares pursuant to the general mandate to issue shares granted to our Directors as described in “Appendix IV—Statutory and General Information” or otherwise, upon the expiration of restrictions set out above. We cannot predict the effect, if any, that any future sales of Shares by our Controlling Shareholders, or the availability of Shares for sale by our Controlling Shareholders, or the issuance of Shares by the Company may have on the [REDACTED] of the Shares. Sale or issuance of a substantial amount of Shares by our Controlling Shareholders or us, or the market perception that such sale or issuance may occur, could materially and adversely affect the prevailing [REDACTED] of the Shares.

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We cannot assure you that we will declare and distribute any amount of dividends in the future and dividends distributed in the past may not be indicative of our dividend policy in the future.

Our ability to declare future dividends will depend on the availability of dividends, if any, received from our operating subsidiaries. Under applicable laws and the constitutional documents of our operating subsidiaries, the payment of dividends may be subject to certain limitations. The calculation of certain of our operating subsidiaries’ profit under applicable accounting standards differs in certain respects from the calculation under HKFRSs. As a result, our operating subsidiaries may not be able to pay a dividend in a given year even if they have profit as determined under HKFRSs. Accordingly, since we derive all of our earnings and cash flows from dividends paid by our operating subsidiaries, we may not have sufficient distributable profit to pay dividends to our Shareholders. In addition, any future dividend declaration and distribution will be at the discretion of our Directors and will depend on our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our Directors deem relevant. Any declaration and payment as well as the amount of dividends will also be subject to our Articles of Association and Cayman Islands laws, including, where required, the approvals from our Shareholders and/or our Directors. Our Shareholders at a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. Moreover, our Directors may from time to time pay such interim dividends as our Board considers to be justified by our profits and overall financial requirements, or special dividends of such amounts and on such dates as they think appropriate. In any event, no dividend may be declared or paid other than out of profits or from any reserve set aside from profits which our Directors determine is no longer needed, or share premium. As a result, we cannot assure you that we will make any dividend payments on our Shares in the future.

We have discretion as to how we will use the [REDACTED] from the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return. For details of our intended use of [REDACTED], see “Future Plans and Use of [REDACTED].” However, our management will have discretion as to the actual application of our [REDACTED]. You are entrusting your funds to our management, upon whose judgment you must depend, for the specific uses we will make of the [REDACTED] from this [REDACTED].

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in pro forma net tangible asset value. In order to expand our business, we may consider [REDACTED] and [REDACTED]

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additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than [REDACTED].

We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Articles of Association and by the Cayman Companies Act and common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, actions by minority Shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority Shareholders may be located. See “Appendix III—Summary of the Constitution of the Company and Cayman Islands Company Law.”

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Controlling Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

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 sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Sole Sponsor, the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisers 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 risks and uncertainties and are subject to change and should not be unduly relied upon.

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Investors should read the entire document and should not consider any particular statements in this document or in published media reports without carefully considering the risks and other information contained in this document.

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 investors 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.

You should rely solely upon the information contained in this document in making your [REDACTED] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [REDACTED] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, prospective investors should not rely on any such information, reports or publications in making their decisions as to whether to [REDACTED] our [REDACTED].