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## RISK FACTORS

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*You should carefully consider all of the information in this prospectus, including the following risk factors before making any investment decision in relation to the Offer Shares. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. The market price of the Offer Shares could fall significantly due to any of these risks, and you may lose all or part of your investment.*

### RISKS RELATING TO OUR BUSINESS AND INDUSTRY

**We rely on the sales of a limited number of proprietary product and promotion products for business partners, especially in Mainland China, which account for a substantial portion of our total revenue. If we are unable to maintain the sales volume, pricing levels and profit margins of such products due to factors such as competition or change in government regulations, our operations, revenue and profitability could be adversely affected.**

Our revenue is highly dependent on the sales of our proprietary product Zadaxin and certain promotion products for business partners, including Farlutal, Methotrexate, Estracyt, Holoxan, Mesna and Endoxan. Revenue from such sources accounted for 96.4%, 97.8%, 97.4%, 97.4% and 99.5% of our total revenue in 2017, 2018 and 2019 and the nine months ended September 30, 2019 and 2020, respectively. Zadaxin, our top product in terms of revenue contribution, accounted for 91.7%, 83.0%, 79.0%, 80.2% and 83.7% of our total revenue in 2017, 2018 and 2019 and the nine months ended September 30, 2019 and 2020, respectively.

We generated a substantial majority of our revenue from Zadaxin in Mainland China in recent years and we expect that such concentration will continue in the foreseeable future. We cannot assure you that we will successfully increase our sales in the overseas markets. As a result, we may be particularly susceptible to factors affecting our sales volume, pricing level or profitability of Zadaxin in Mainland China, including removal or exclusion from provincial or other government-sponsored medical insurance programs, unfavorable legal, regulatory or policy changes such as the implementation and expansion of the National Key Drug List for Monitoring and Prescription Control (Chemical and Biological Products) (《國家重點監控合理用藥藥品目錄(化藥及生物製品)》) jointly issued by the NHC and National Administration of Traditional Chinese Medicine (國家中醫藥管理局), which currently includes the thymic hormone drug Thymopentin, and potential inclusion or exclusion of Zadaxin on such list, fluctuation in prices, concerns over adjuvant therapies, and our efforts in expanding the clinical adoptions of Zadaxin. In particular, Zadaxin was approved in China in 1996 as the first branded thymalfasin drug in the market. Given their finite duration, certain patents we used to hold for Zadaxin's indication (such as chronic hepatitis B) had already expired as of the Latest Practicable Date. As a result, we face competition from manufacturers of generic thymalfasin and other thymic hormone drugs in Mainland China. See "Industry Overview — The Thymic Hormones Market — Competitive Landscape." As of the Latest Practicable Date, one generic drug to Zadaxin (Jitai (基泰), the generic thymalfasin drug manufactured by ShuangCheng Pharmaceuticals) had passed the consistency evaluation for quality and efficacy, and four generic drugs to Zadaxin were awaiting consistency evaluation results. Generic drugs that have passed the consistency evaluation may enjoy certain market privileges. For example, generic drugs that have passed the consistency evaluation are allowed to participate in the volume-based procurement. As of

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the Latest Practicable Date, thymalfasin was not included in the volume-based procurement; however, if thymalfasin is included in the volume-based procurement in the future, though we could either participate or decline to participate in the bidding for Zadaxin, Jitai may choose to participate in the bidding and may be included in the volume-based procurement, resulting in its price decline. Therefore, passing of the consistency evaluation by any generic drug to Zadaxin, including Jitai, may subject us to increased competition, may create greater pressure on the market share and price level of Zadaxin, and consequently, may adversely affect our operations, revenue and profitability. Although we believe Zadaxin is expected to enjoy market advantage in the near future in China as we continue to diversify our sales through retail pharmacies and reduce our reliance on sales to hospitals, expand Zadaxin's indications and clinical adoptions through lifecycle management, and collaborate with commercial insurance companies to increase Zadaxin's insurance coverage, our operations, revenue and profitability could be adversely affected if our sales of Zadaxin does not meet expectation.

As our revenue is, and we expect will continue to be, concentrated in a limited number of products, we may be particularly susceptible to factors adversely affecting the sales volume, pricing level or profitability of any of the products we generate revenue from. Factors that could adversely affect the sales volume, pricing level and profitability of the products we sell include: exclusion from, or reduced coverage under, the provincial or other government-sponsored medical insurance programs, the impact of government pricing regulations, competition and lack of success in the centralized tender process necessary for sales to PRC public hospitals and other medical institutions, sales of substitute products by competitors, interruptions in the supply of raw materials, increases in the cost of raw materials, issues with product quality or side effects, intellectual property infringements, adverse changes in our sales and distribution network, and unfavorable policy, regulatory or enforcement changes. Many of these factors are outside of our control, and any factor adversely affecting the sales volumes, pricing levels and profit margins of our products could adversely affect our operations, revenue and profitability.

**We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors selling competing drugs such as substitute or generic drugs and new innovative drugs, which could subject us to the pressure of price reduction and adversely affect our operations, revenue and profitability.**

We operate in a highly competitive environment. Our products primarily compete on the basis of efficacy, price and general market acceptance. Our key competitors are large national and regional manufacturers of pharmaceutical products, including large state-owned pharmaceutical companies. We also compete with multi-national pharmaceutical companies. For our proprietary product Zadaxin, we may face competitions from competing products, such as other approved thymic hormone drugs and alternatives, including Thymopentin and Thymosin. See "Industry Overview — The Thymic Hormones Market."

Our competitors may be able to successfully develop or market effective substitutes for our products for a number of reasons, including:

- the patents for our current products, as well as a substantial portion of the product candidates we intend to develop, generally relate to the products' delivery systems,

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compositions, preparation methods or production processes, and do not cover the underlying active pharmaceutical ingredients. Therefore, our competitors may formulate substitute products utilizing the same active pharmaceutical ingredients. Also, given the finite duration of patents, certain patents we used to hold for Zadaxin's indication (such as hepatitis B) had already expired as of the Latest Practicable Date, and the five patents of Zadaxin we currently hold in China have expiry dates ranging from 2021 to 2030. We also hold 34 patents of Zadaxin with varying expiry dates in jurisdictions outside China, such as the United States, Italy, the United Kingdom, Japan, Germany and France. See "Appendix V — Statutory and General Information — B. Further Information About Our Business — 2. Intellectual Property Rights of Our Group — (c) Patents." We may face competition from generic or biosimilar medications, and may not be able to develop or market Zadaxin for the relevant indication or clinical adoption exclusively once the patents expire, which could have a material adverse impact on any potential sales of Zadaxin;

- our proprietary product Zadaxin has been sold in the PRC market for more than 20 years, which makes it susceptible to competing drugs such as substitute or generic drugs and new innovative drugs that are more effective clinically or cost-wise as a result of technological developments, changes in treatment protocols and other medical advances that have occurred subsequent to the initial development of our products. See "Business — Competition." We could therefore be subject to the pressure of pricing and volume of Zadaxin against the competing drugs, and any potential sales of Zadaxin, our operations, revenue and profitability could be adversely affected;
- our products typically target conditions that are in high demand for medical treatment in China, and, as a result, our competitors, including foreign pharmaceutical companies and large state-owned pharmaceutical companies, some of whom may have greater financial and development resources than us, may elect to focus their resources on developing, importing or in-licensing and marketing products in the PRC that are substitutes for our products or in areas where we are developing product candidates or new indications for our existing products; and
- many of our competitors, including foreign pharmaceutical companies and large state-owned pharmaceutical companies, have more extensive sales and marketing resources than us, which enables them to have better access to hospitals and medical institutions in order to gain market acceptance for their substitute products.

Our products may also face increased competition from substitute products manufactured by overseas pharmaceutical companies that are seeking to access or further penetrate the PRC market. To the extent that our competitors' substitute products are, or are perceived to be, more clinically or cost-effective than ours, or otherwise gain wider market acceptance than any of our pharmaceutical products, this could adversely affect our sales volumes and pricing levels for the relevant products.

In addition, there may also be significant consolidation in the pharmaceutical industry among our competitors, or alliances developed among competitors that may rapidly acquire significant

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market share. If we fail to effectively compete with our competitors or adjust to structural changes in the pharmaceutical industry, our revenue and profitability may be materially and adversely affected.

**We are dependent upon Sinopharm as the exclusive importer and distributor of Zadaxin; because of China's tiered method of importing and distributing finished pharmaceutical products, our results may vary substantially from one period to the next.**

Imported products in China, including Zadaxin and other imported products, are distributed through a tiered method of importing and distributing finished pharmaceutical products. At each port of entry, and prior to moving the product forward to the distributors, government-licensed importing agents must process and evaluate each imported product shipment to determine whether it satisfies China's quality assurance requirements. In order to efficiently manage this process, the importing agents typically place large, and therefore relatively few, orders within an annual period. Therefore, sales to an importing agent can vary substantially from period to period depending on the size and timing of the orders, which has in the past caused, and may in the future cause our revenue to fluctuate. In addition, the price at which Sinopharm procures Zadaxin from us is subject to fluctuation in end-point sales price at which the product will be sold to hospitals or pharmacies, which may cause our revenue to fluctuate. We rely on Sinopharm to import Zadaxin to China and distribute Zadaxin in China. As a result, our receivables from Sinopharm are material, and if we were unable to collect receivables from Sinopharm, our operations, revenue and cash flow would be adversely affected.

Generally, our importers are not obligated to place purchase orders for our product, and if they determined for any reason not to place purchase orders, we would need to seek alternative licensed importers, which could cause fluctuations in our revenue. As a result of our agreement granting certain exclusive importation rights to Sinopharm for Zadaxin, we are dependent upon Sinopharm's performance of its obligations under that agreement. We have a long-standing and, we believe, stable relationship with Sinopharm; however, if Sinopharm were unable to adequately perform its obligations under, or breached the agreement, our operations would be adversely affected.

**We may experience difficulties in our sales efforts as a result of pricing regulations or other policies such as volume-based procurement that are intended to reduce healthcare costs, which could subject us to pricing and volume pressures and adversely affect our operations, revenue and profitability.**

The products we sell are subject to increasing pricing pressures, particularly in China. Government regulations on pricing and limitations on patient access to the products we sell impact our business, and our future results could be adversely affected by changes in such regulations or policies.

The PRC government is increasing its efforts to reduce overall healthcare costs, including regulating prices on pharmaceutical products by establishing a centralized tender process or centralized procurement mechanism, revising the NRDL or provincial medical insurance drug catalogues and strengthening regulation of medical and pricing practices. Individual provinces in

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China and, in some cases, individual hospitals can and have established pricing requirements for a product to be included on formulary lists or imposed price reductions as part of the provincial tender process. In some cases, these price limits may be significantly lower than prices at which our distributors sell Zadaxin and other products we sell, which consequently may reduce sales to certain hospitals and could adversely affect our future sales.

In May 2015, pursuant to the Notice on Issuing the Opinion on Promoting Pharmaceutical Pricing Reform (《關於印發推進藥品價格改革意見的通知》) issued by seven PRC state agencies, including the NDRC and the NMPA, government price controls on most pharmaceutical products were lifted effective as of June 1, 2015. As a result, prices of most pharmaceutical drugs are currently determined mainly by market competition through the centralized tender process at the provincial level, without being subject to price ceilings set by the NDRC. However, there is no assurance that such market-based pricing mechanism will result in higher product pricing compared to government-controlled pricing, as competition from other manufacturers, particularly those offering the same products at more competitive prices may force us to lower prices of the products we sell upon commercialization to the previous government-controlled price levels. In addition, some new methods are used in recent centralized tender process at the provincial level, such as renegotiation of prices between hospitals and distributors or manufacturers after the retail prices are determined by the statutory tender process, which may further increase pricing pressure. See “— If we are unable to win bids to sell our proprietary product or in-licensed products to PRC public medical institutions through the centralized tender process, we will lose market share and our operations, revenue and profitability could be adversely affected.” There is no guarantee that the new policies would not create any downward pressure on the prices of our existing and future products.

The changing pricing regulations in China, whether operating at a national, provincial or institutional level, as well as regulation of import of pharmaceutical products, may reduce retail prices of, and our own revenue from, Zadaxin and other products we sell, and we expect that pricing pressure will continue. While the regulatory mechanisms are changing and the ultimate outcome is uncertain, and while we have been able to mitigate the impact of prior price reductions on our overall business, prices could be reduced to levels significantly below those that would prevail in an unregulated market, limit the volume of product which may be imported and sold, or place high import duties on the product, any of which may limit the growth of our revenues or cause them to decline.

On November 15, 2018, the Joint Procurement Office led by the National Healthcare Security Administration published the Papers on Centralized Drug Procurement in “4+7 Cities” (the “**Papers**”), which launched the volume-based procurement of public medical institutions. The Papers list 31 drugs for this pilot scheme together with an intended quantity commitment for each drug. The domestic drug manufacturers and the domestic general agents for imported drugs in China are invited to bid to supply the drugs to public medical institutions in the “4+7 Cities.” The move is aimed at reducing drug prices and may potentially impact how drugs are priced and procured in China. On January 1, 2019, the General Office of the State Council also published the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which provides additional detailed measures in

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the implementation of the volume-based procurement in the “4+7 Cities.” See “Regulatory Overview — The Volume-based Procurement in ‘4+7 Cities’ and Wider Areas.” Furthermore, there are uncertainties with respect to future drug coverage of this national pilot scheme and the scheme may be promoted to provincial levels as well. Although the pilot scheme requires that public medical institutions should give priority to the use of selected products for centralized procurement and ensure that the usage at the agreed procurement quantity is completed within one year, the public medical institutions may reserve up to 30% of its total procurement volume for unselected products, leaving considerable volume share for unselected products. However, there can be no assurance that we may have drugs added to this national pilot scheme in the future to increase our sales volume, while our competing drugs may be added to the scheme if they pass the consistency evaluation, which may in turn result in increased pricing and volume pressures on us.

As of the Latest Practicable Date, none of our marketed products were included in the volume-based procurement for sales to PRC public medical institutions, and other than bivalirudin, none of the corresponding chemical compounds of our products were included in the volume-based procurement bidding catalogue. Only one generic drug to Zadaxin (Jitai (基泰), the generic thymalfasin drug manufactured by ShuangCheng Pharmaceuticals) had passed the consistency evaluation for quality and efficacy, and only innovative drugs, as well as generic drugs that have passed the consistency evaluation, may be included in the volume-based procurement. Currently, the volume-based procurement scheme has limited impact on our operations, revenue and profitability. The bidding for the third round of the volume-based procurement which was completed in August 2020 resulted in significant price decline of the drugs included, in certain cases as much as 80%. With the expansion of the volume-based procurement scheme, including the fourth round of the volume-based procurement, which included bivalirudin, the chemical compound of Angiomax in the bidding catalogue, and as the scheme embodies a PRC regulatory aim to reduce the drug prices and the burden of pharmaceutical costs on patients, if any of our products or their corresponding chemical compounds is included in the volume-based procurement, though we could either participate or decline to participate in the bidding, our competing generic drugs, if such generic drugs pass the consistency evaluation, may choose to participate in the bidding and be included in the volume-based procurement, resulting in significant price decline of the relevant drugs, and we may experience increased pricing pressures and our operations, revenue and profitability could be materially and adversely affected.

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In terms of volume, sales of Zadaxin accounted for 20.4% of the thymalfasin market in China in 2019, according to Frost & Sullivan. The following table sets forth a sensitivity analysis illustrating the potential impact of the hypothetical inclusion of thymalfasin in the volume-based procurement on the revenue from our sales of Zadaxin for the year ended December 31, 2019. The sensitivity analysis is only a hypothetical illustration on the average selling price decreases, market share changes and the resulting potential impact on the revenue from the sales of Zadaxin, and therefore by no means represents our actual business strategy and decision in response to the volume-based procurement. We will decline to participate in the volume-based procurement if the participation will result in significant price decrease of Zadaxin.

	<b>Zadaxin's market share in the thymalfasin market in China in terms of volume</b>						
	<b>5%<sup>(1)</sup></b>	<b>10%<sup>(1)</sup></b>	<b>15%<sup>(1)</sup></b>	<b>30%<sup>(2)</sup></b>	<b>40%<sup>(2)</sup></b>	<b>50%<sup>(2)</sup></b>	
	<b>Fluctuations of revenue from our sales of Zadaxin</b>						
	<b>RMB'000</b>	<b>RMB'000</b>	<b>RMB'000</b>	<b>RMB'000</b>	<b>RMB'000</b>	<b>RMB'000</b>	
	<b>Assuming we decline to participate in the volume-based procurement</b>			<b>Assuming we participate in the volume-based procurement and win the bid</b>			
<b>Zadaxin's average selling price decrease</b>	<b>0%<sup>(1)</sup></b>	(945,963) <sup>(1)</sup>	(638,832) <sup>(1)</sup>	(331,701) <sup>(1)</sup>	N/A <sup>(4)</sup>	N/A <sup>(4)</sup>	N/A <sup>(4)</sup>
	<b>30%<sup>(2)</sup></b>	N/A <sup>(3)</sup>	N/A <sup>(3)</sup>	N/A <sup>(3)</sup>	36,856 <sup>(2)</sup>	466,839 <sup>(2)</sup>	896,822 <sup>(2)</sup>
	<b>60%<sup>(2)</sup></b>	N/A <sup>(3)</sup>	N/A <sup>(3)</sup>	N/A <sup>(3)</sup>	(515,980) <sup>(2)</sup>	(270,275) <sup>(2)</sup>	(24,570) <sup>(2)</sup>
	<b>90%<sup>(2)</sup></b>	N/A <sup>(3)</sup>	N/A <sup>(3)</sup>	N/A <sup>(3)</sup>	(1,068,815) <sup>(2)</sup>	(1,007,389) <sup>(2)</sup>	(945,963) <sup>(2)</sup>

*Notes:*

- (1) Based on the assumption that we decline to participate in the volume-based procurement, resulting in Zadaxin's unchanged average selling price and market share loss compared to its actual 20.4% market share of the thymalfasin market in China in 2019 in terms of volume, and corresponding decrease in revenue from the sales of Zadaxin. For instance, if we decline to participate in the volume-based procurement, resulting in Zadaxin's unchanged average selling price and market share drop to 15%, our revenue from the sales of Zadaxin will decrease by RMB331.7 million.
- (2) Based on the assumption that we participate in the volume-based procurement and win the bid, resulting in Zadaxin's average selling price decrease and market share gain compared to its actual 20.4% market share of the thymalfasin market in China in 2019 in terms of volume, and corresponding change in revenue from the sales of Zadaxin. For instance, if we participate in the volume-based procurement and win the bid, resulting in Zadaxin's average selling price decrease by 30% and market share increase to 30%, our revenue from the sales of Zadaxin will increase by RMB36.9 million.
- (3) Not applicable as under the assumption that we decline to participate in the volume-based procurement, Zadaxin's average selling price will not decrease and will remain unchanged.
- (4) Not applicable as under the assumption that we participate in the volume-based procurement and win the bid, Zadaxin's average selling price will decrease and will not remain unchanged.

For the nine months ended September 30, 2020, sales volume through our GTP model, which is outside the traditional public hospital and public medical institution sales channels affected by the volume-based procurement, accounted for more than 50% of our total sales volume of Zadaxin. We will continue to expand our sales through the GTP model and reduce our reliance on the traditional public hospital and public medical institution sales channels to lessen the impact of potential inclusion of thymalfasin in the volume-based procurement.

If the retail prices of the products we sell decline due to government pricing regulations, competition or other factors, there can be no assurance that we will be able to mitigate the adverse effects of such price reductions without incurring substantial expenses to improve the products we

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sell, and our operations, revenue and profitability could be materially and adversely affected. See “Financial Information — Description of Major Components of Our Results of Operations” for average selling prices of the products we sell during the Track Record Period.

**If we, our employees, distributors or suppliers engage, or are perceived to engage, in misconduct or breaches, including corrupt or bribery practices, leakage of confidential information or unfair competition, or if we, our employees or business partners are involved in negative publicity or allegations, our operations and reputation could be adversely affected, and we could be exposed to regulatory investigations, costs and liabilities.**

We are subject to risks in relation to actions taken by us, our employees, distributors or affiliates that may constitute violations of applicable anti-corruption and other related laws. There have been instances of corrupt practices in the pharmaceutical industry in recent years, including, among other things, provision of kickbacks, bribes or other illegal gains or benefits to pharmacies, hospitals and medical practitioners from manufacturers, distributors and pharmacies in connection with the prescription of pharmaceutical products. Any allegations of such behavior against us, our employees, distributors or affiliates or the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation and business prospects. For instance, in August 2010, the U.S. Securities and Exchange Commission (“SEC”) and the U.S. Department of Justice (“DOJ”) commenced an investigation (the “Investigation”) into SciClone US’s potential violations of the Foreign Corrupt Practices Act (“FCPA”) in conducting business in China. In February 2016, SciClone US settled with the SEC pursuant to a cease-and-desist order (the “Order”) published by the SEC, resolving the Investigation. Around the same time, the DOJ confirmed that it declined to pursue further action. See “Business — Legal and Compliance — Legal Proceedings — SEC FCPA Investigation and Settlement.”

We do not and cannot fully control the conducts of our employees, distributors or suppliers. Our employees, distributors or suppliers 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 or distributors engage in corrupt or other improper conduct that results in violation of applicable anti-corruption laws in the PRC or other 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, distributors or suppliers, which could expose us to regulatory investigations and penalties. Actions taken by the PRC regulatory authorities or the courts that provide an interpretation of the PRC 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.

Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Purchase and Sales of Medicines (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was



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promulgated by the NHC, if we are involved in criminal, investigational or administrative procedures for commercial bribery, we will be listed in the adverse records of commercial bribes by the relevant PRC 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 a specific territorial scope for two years; and if we are listed in the adverse records of commercial bribes 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.

In addition, our business may be materially and adversely affected if our employees breach the non-disclosure, non-compete and non-solicitation clauses in their employment agreements, if any.

**Our revenues are dependent on our obtaining or maintaining of regulatory licenses and compliance with country-specific regulations, including renewing our drug import licenses and compliance with the Chinese Pharmacopeia.**

Our revenue is dependent on receipt and maintenance of regulatory permits, licenses and approvals and compliance with other country-specific regulations in a timely manner. For example, we have received regulatory approvals to import and market our proprietary product and in-licensed products in China. In order to continue our sales to China, we need to maintain these approvals, known as Import Drug Licenses, which allow for the importation and commercial sale of a pharmaceutical product manufactured outside of China. Our Import Drug Licenses need to be renewed every five years for us to continue our ability to import and sell our proprietary product and in-licensed products into China. Although Import Drug License renewals in the past were obtained successfully, there is no assurance that we will receive renewals in the future when applied for or that the renewals will not be conditioned or limited in ways that limit our ability to import and sell products into China.

Our ability to obtain a renewal of or maintain our regulatory permits, licenses and approvals from the NMPA could be adversely affected due to changes in policies and practices at the NMPA in the review process, including with respect to potential requirements for additional technical information and product specification changes regarding the products we sell.

The NMPA and other regulatory agencies may change their internal administrative rules in ways that may delay or complicate the regulatory approval process. Those changes are not always disclosed or made known to us and we may experience unexpected delays or additional costs as a result of such changes. Any change in our ability to obtain or renew regulatory permits, licenses or approvals could have an adverse effect on our revenue and results of operations.

The products we sell are subject to rigorous regulation in the jurisdictions where they are sold, including the standards established by the Chinese Pharmacopoeia (《中華人民共和國藥典》), or ChP, in China. The ChP is an official compendium of drugs in China and sets the standards of purity, description, test, dosage, precaution, storage, and the strength for each drug in China. If the products we sell fail to meet relevant specifications, including ChP specifications, during routine customs testing as such specifications may be revised from time to time, our Import Drug Licenses, which

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allow the importation for commercial sales, may be revoked, which would result in a significant loss of revenue and materially adversely affect our business.

**We are subject to changing legal and regulatory requirements in the pharmaceutical industry, and new laws, rules and regulations may adversely affect our operations, revenue and profitability or impose additional compliance burdens on us.**

The pharmaceutical industry in China is subject to extensive government regulation and supervision as well as monitoring by government authorities. In particular, the current regulatory framework addresses all aspects of a pharmaceutical company's operations, including approval, production, licensing, certification requirements and procedures, periodic renewal and continued inspection and reassessment processes, registration of new drugs, quality control, labelling, pricing and advertising of pharmaceutical products, and environmental protection. Any violation of relevant laws, rules and regulations may constitute a criminal offense under certain circumstances. Certain other laws, rules and regulations may affect the pricing, demand and distribution of the pharmaceutical products we sell, such as those relating to procurement, prescription and dispensing of essential and other drugs by hospitals and other medical institutions, pharmacies, government funding for private healthcare and medical services, and the inclusion of products in the NRDL or provincial medical insurance drug catalogues. In addition, the pharmaceutical distribution, pharmaceutical retail and healthcare services in China are each subject to extensive and changing government regulations and supervision. Any unfavorable regulatory changes in these industries may increase our compliance burden and materially and adversely affect our business, profitability and prospects. In addition, we cannot assure you that the PRC government will adopt policies supporting the pharmaceutical industry in China. For example, since July 2015, the NMPA has introduced a number of measures to deal with the drug applications backlog. On July 22, 2015, the NMPA issued the Notice in relation to the Self-review of Clinical Trials Data of Pharmaceutical Products (《關於開展藥物臨床試驗數據自查核查工作的公告》), which required applicants to self-review the clinical trials data of 1,622 listed drugs with pending applications for manufacturing or importation approval. On July 31, 2015, the NMPA issued the Announcement on Consultation on Policies in relation to Swiftly Resolving Drug Applications Backlog (《關於徵求加快解決藥品註冊申請積壓問題的若干政策意見的公告》), according to which the NMPA planned to apply stringent standards to review and approve current drug applications. In addition, on November 11, 2015, the NMPA issued the Announcement on Certain Policies in relation to the Review and Approval of Drug Applications (《關於藥品註冊審評審批若干政策的公告》), which set out ten key points to be applied in the process of reviewing and approving drug applications and clinical trials, with an emphasis on the accuracy of clinical trial data and drug effectiveness. The combination of these policies indicates that pharmaceutical companies need to conduct self-reviews of their drug applications and data to determine if they meet the stringent standards set by the NMPA. Failure to meet NMPA requirements could result in the relevant applicant having to withdraw its drug application and resubmit the relevant drug application only when NMPA requirements are met. The stringent standards in respect of drug applications may delay our applications in relation to our future products or require us to withdraw our applications.

In March 2016, the General Office of the State Council issued the Opinion on Conducting the Consistency Evaluation of the Quality and Efficacy of 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 “**March 2016 Opinion**”), which requires pharmaceutical

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manufacturers to evaluate the quality and efficacy of certain of their generic drugs within the prescribed time limits. In August 2017, the NMPA issued the Announcement of the China Food and Drug Administration on Relevant Matters Concerning the Consistency Evaluation for Quality and Efficacy of Generic Drugs (國家食品藥品監督管理總局關於仿製藥質量和療效一致性評價工作有關事項的公告), which sets out procedures for the application, approval, inspections and test of the consistency evaluation as required under the March 2016 Opinion. In December 2018, the NMPA issued the Announcement on the Relevant Matters Concerning the Quality and Efficacy Consistency Evaluation of Generic Drugs (《國家藥品監督管理局關於仿製藥質量和療效一致性評價有關事項的公告》) which removed the uniform timelines for the oral solid preparations of chemical generic drugs included in the National Essential Drugs List (2012 Edition) to complete the consistency evaluation. As these are new regulations, there remains significant uncertainty relating to the substantive and procedural requirements of the evaluation process, and the interpretation of such written requirements and procedures. As of the Latest Practicable Date, one generic drug to Zadaxin (Jitai (基泰), the generic thymalfasin drug manufactured by ShuangCheng Pharmaceuticals) had passed the consistency evaluation for quality and efficacy. Passing of the consistency evaluation by any generic drug to Zadaxin may adversely affect our operations, revenue and profitability.

In addition, on November 15, 2018, the Joint Procurement Office led by the National Healthcare Security Administration launched a national pilot scheme for volume-based procurement. See “Regulatory Overview — The Volume-based Procurement in ‘4+7 Cities’ and Wider Areas.” The implementation of this procurement scheme may result in increased pricing pressure on us. See “— We may experience difficulties in our sales efforts as a result of pricing regulations or other policies such as the volume-based procurement that are intended to reduce healthcare costs, which could subject us to pricing and volume pressures and adversely affect our operations, revenue and profitability.” Legal and regulatory changes in the PRC pharmaceutical industry could result in increased costs and lowered profit margins for distributors of pharmaceutical products. Any legal and regulatory changes could also lead to a decrease in the amount of products purchased by our customers and/or the price of the products we sell. We cannot assure you that we will be able to effectively and promptly respond to legal and regulatory changes in the future at reasonable costs, and such failure may have a material and adverse effect on our operations, revenue and profitability.

While we intend to increase the sales of Zadaxin and other pharmaceutical products through the adoption of the GTP model, there are certain legal and regulatory restrictions with regard to online sales of drugs. As of the Latest Practicable Date, of all the products we sold, only Zadaxin was provided on the GTP platform, which is not subject to such restrictions. However, there can be no assurance that other products we sell will not be subject to these restrictions, and our business prospects could be adversely affected due to the restrictions. See “Regulatory Overview — Laws and Regulations in Relation to Drugs — Distribution of Drugs — Drug Operation Permit.”

**We rely on certain business partners for sales of promotion products. The termination of any distribution or promotion and sales agreement with our business partners may adversely affect our operations, revenue and profitability.**

Sales of promotion products for business partners depends on our relationships with leading multi-national pharmaceutical manufacturers such as Baxter and Pfizer. Products we distribute or

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promote for Baxter and Pfizer accounted for 7.0%, 15.0%, 18.4%, 17.2% and 15.8% of our total revenue in 2017, 2018, 2019 and the nine months ended September 30, 2019 and 2020, respectively. We typically distribute and promote such products pursuant to distribution or promotion and sales agreements entered into directly between us and our business partners. We typically enter into agreements with our business partners for sales of promotion products for business partners for a prescribed term. See “Business — Products and Services.” There can be no assurance that our business partners will continue to sell products to us on commercially reasonable terms or at all. We also cannot assure you that we will be able to establish new business partner relationships, or extend existing relationships with our business partners when our agreements with them expire. Furthermore, certain of our agreements with our business partners may be terminated at will prior to their specified termination dates, our business partners may alter the specifications and/or types of products they sell to us, and our business partners are under no obligation to continue manufacturing the products. If we are unable to maintain our relationships with our key business partners, or any of our distribution or promotion and sales agreements with our key business partners are terminated, our operations, revenue and profitability could be materially and adversely affected.

**We rely on certain licensors with respect to our in-licensed products. If we cannot maintain our relationships with such licensors, or if such licensors are involved in intellectual property disputes for our in-licensed products, our ability to renew the exclusive promotion and selling rights of our existing in-licensed products upon expiry, or obtain promotion and selling rights for new products could be adversely affected.**

We depend on our relationships with our licensors with respect to our in-licensed products. We cannot assure you that we will be able to maintain our relationships with our licensors or that we will be able to renew our existing licensing agreements when they expire. Our failure to maintain such relationships or obtain such renewals could materially and adversely affect our operations, revenue and profitability.

Furthermore, we or our licensors may be subject to claims that former employees, collaboration partners or other third parties have an interest in our in-licensed patents. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights or our patent claims may be narrowed, invalidated or held unenforceable. In addition, if our licensors are unsuccessful in any inventorship disputes to which they are subject, we may lose valuable intellectual property rights, such as the exclusive right to use our in-licensed patents. If we or our licensors are unsuccessful in any interference proceedings or other priority or inventorship disputes, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could materially adversely affect our operations, revenue, profitability and business prospects. Even if we or our licensors are successful in interference proceedings or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

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**If the products we sell are removed or excluded from provincial or other government-sponsored medical insurance programs, patients in certain income classes may not be able to afford our products and our operations, revenue and profitability could be adversely affected.**

Under medical insurance programs in the PRC, patients are entitled to reimbursement of all or a portion of the cost of pharmaceutical products listed in the NRDL, relevant provincial medical insurance catalogues or included in provincial insurance schemes regarding special medications for the treatment of major diseases. See “Regulatory Overview — Medical Insurance Catalogue.” Consequently, the inclusion or exclusion of a pharmaceutical product in or from any of the NRDL or provincial medical insurance catalogues or any limitation imposed on the coverage of a pharmaceutical product will significantly affect patient demand in the PRC.

The inclusion of pharmaceutical products by the relevant PRC government authorities in the NRDL or provincial medical insurance catalogues is based on a variety of factors, including efficacy, safety and price, which may be outside of our control. Moreover, the relevant PRC government authorities may also, from time to time, review and revise, or change the scope of reimbursement for, the products that are listed in any medical insurance catalogue. There can be no assurance that any of our products currently listed in these medical insurance catalogues will be or remain listed, or that changes in the scope of reimbursement will not negatively affect our product sales. If any of our products or their indications are removed from any medical insurance catalogue, or if the scope of reimbursement is reduced, demand for our products may decrease and our operations, revenue and profitability could be adversely affected.

**If we are unable to win bids to sell our proprietary product or in-licensed products to PRC public medical institutions through the centralized tender process, we will lose market share and our operations, revenue and profitability could be adversely affected.**

The majority of the pharmaceutical products we sell to our distributors are then sold to public hospitals and other public medical institutions in China. Each public medical institution in China must generally procure drugs through a provincial centralized drug purchase platform and make substantially all of its purchases of pharmaceutical products through a centralized tender process. We submit bids in a centralized tender process to supply our products to these institutions at specified prices. Our bids are generally considered on the basis of price relative to substitute products and their clinical effectiveness, as well as the quality of our products and services, among other things. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public hospitals and other public medical institutions at the bid prices, which is the primary determinant of the prices at which we sell our products to our distributors. The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. See “Business — Pricing for Products and Services — Regulatory Regimes Affecting Prices of Pharmaceutical Products.”

Our sales volumes and profitability depend on our ability to successfully differentiate our products and price of our bids in a manner that enables us to succeed in the centralized tender process at profitable levels. If we are unable to do so, we will lose the revenue associated with the

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sale of the affected pharmaceutical products to the relevant PRC public hospitals and other public medical institutions, which may have a material and adverse impact on our market share and operations. Potential changes in regulations of provincial and municipal tender processes may further increase the public medical institution procurement covered through the tender processes and limit the profits available to pharmaceutical companies, which may further affect our operations, revenue and profitability.

We may fail to win bids in a centralized tender process due to various factors including reduced demand for the relevant product, uncompetitive bidding prices, failure to meet certain quality requirements, insufficient service quality to meet tender requirements, the relevant product is perceived to be less clinically effective than competing products, or our services or other aspects of our operations are perceived to be less competitive. If the products we sell are not selected in the centralized tender 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, revenue and profitability could be adversely affected.

### **We may incur unexpected charges relating to our operations.**

Certain post-production processes, including transportation, storage, warehousing and usage, may adversely affect the quality of our pharmaceutical products. We generally rely on transport operators for delivery of our products. Delivery disruptions for reasons beyond our control, including weather conditions, political turmoil, social unrest and strikes, could lead to delayed deliveries. The nature of pharmaceutical products may also mean that poor handling or storage by pharmacies, hospitals, patients or transport operators could result in damage to our products, including contamination or degeneration. For example, prolonged exposure to heat or sunlight may damage certain pharmaceutical products. Some of these processes are managed by third parties, over which we have limited control. In particular, once we have sold our products to distributors, we have limited control over how our distributors store and transport our products.

If, as a result of such post-production processes, our pharmaceutical products are deemed or proven to be unsafe, ineffective, defective or contaminated, this may result in product liability or product recalls. Even if a situation does not necessitate a product recall, we cannot assure you that product liability claims will not be asserted against us as a result. Any claims relating to the quality of our pharmaceutical products, regardless of their merit, could adversely affect our reputation, divert the time, resources and attention of our management, and result in material and adverse impact on our operations, revenue and profitability.

Although we have generally experienced minimal product returns and our customers have historically paid all invoiced amounts, we could incur future charges relating to inventory that expires or as a result of customer failures to pay invoiced amounts timely or in full. We may have significant bad debt expenses or write-offs in the future. We could also experience additional charges for potential inventory obsolescence related to other products if we are unable to sell units that are nearing their expiration dates, or for bad debt if other distributors do not pay outstanding receivables in full. Those or similar future events would have an adverse impact upon our operating results.

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**We rely on limited number of suppliers to manufacture our proprietary product and in-licensed products. If our proprietary product and in-licensed products are not produced to the necessary quality standards, or if our suppliers' production capacities cannot satisfy our demands, our operations, reputation, revenue and profitability could be adversely affected.**

We depend on our relationships with our suppliers for a steady supply of our proprietary product and in-licensed products. We typically enter into exclusive supply agreements with our suppliers for a fixed term of five years or more. Most of these agreements renew automatically. However, for various reasons our supply agreements may be terminated pursuant to the terms of the respective agreements or some of their terms may be held unenforceable under applicable laws and regulations.

We cannot assure you that we will be able to maintain our relationships with our suppliers or that we will be able to renew our existing supply agreements when they expire. Our failure to maintain such relationships or obtain such renewals could materially and adversely affect our operations, revenue and profitability.

Our suppliers' products and manufacturing processes are required to meet certain quality standards that we impose. We have established a quality control management system to help prevent quality issues in respect of our products. See "Business — Production and Quality Control — Quality Management" for further details of our quality control management system. Despite our quality control system, we cannot eliminate the risk of errors, defects or failure by our suppliers. We may fail to detect or cure quality defects as a result of a number of factors, many of which are outside our control, including but not limited to:

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

Failure to detect quality defects in our pharmaceutical 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 revenue and profitability.

In addition, our suppliers' manufacturing process is subject to stringent legal and regulatory requirements. If they fail to comply with the relevant rules and regulations and consequently cannot deliver the products to us on time and in the manner as requested by us, we may not be able to find alternative suppliers in a short period of time, which could adversely affect our operations, reputation, revenue and profitability.

During the Track Record Period, we produced Zadaxin through our CMO partner, Patheon Italia with whom we have worked since 2002 under the Manufacturing and Supply Agreement with

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Patheon Italia. We currently rely on Patheon Italia for the supply of Zadaxin. Although we have a long-term and stable business relationship with Patheon Italia, it is not guaranteed that we will be able to maintain our relationship with Patheon Italia or that we will be able to renew the Manufacturing and Supply Agreement with Patheon Italia when it expires. Our failure to maintain such relationship or obtain such renewal or any material disruption to Patheon Italia's operation due to any causes could impact our production, procurement and sales of Zadaxin and our operations, revenue and profitability could be materially and adversely affected.

We have outsourced the production of Zometa under the Supply Agreement dated February 25, 2020 with Novartis, from which we have licensed in Zometa. Novartis will supply us with the products manufactured by Novartis, until we establish our own manufacturing and supply relationship with an international CMO for Zometa. If we are unable to establish such relationship, our sales of Zometa could be impacted and our operations, revenue and profitability could be adversely affected. As of the Latest Practicable Date, we had inventories of Zometa that can last for more than seven months based on our best estimates.

Furthermore, if we plan to increase our production demand in the future, our suppliers' ability to increasing production capacities is subject to a number of risks and uncertainties, including, but not limited to, their ability to obtain the requisite permits, licenses and approvals for the construction and operation of the new production facilities and production lines, the risk of construction delays and delays in equipment procurement, as well as their ability to timely recruit sufficient qualified staff to support the increase in production capacity. Consequently, there can be no assurance that our suppliers will be able to increase production capacities in the manner we contemplate, or at all. In the event our suppliers fail to increase production capacities, we may not be able to capture the potential growth in demand for our products, or to successfully commercialize additional products, each of which could adversely affect our results of operations and business prospects.

**Development of new pharmaceutical products can be time-consuming and costly with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. If we fail to develop and commercialize new pharmaceutical products, our operations, revenue and profitability could be adversely affected.**

Our long-term competitiveness depends on our ability to enhance our existing products and to develop and commercialize new pharmaceutical products. The development process of pharmaceutical products is time-consuming and costly, and there can be no assurance that our development activities will enable us to successfully develop new pharmaceutical products. Our research and development expenses accounted for 6.8%, 5.5%, 5.1%, 4.6% and 3.1% of our total revenue in 2017, 2018 and 2019 and the nine months ended September 30, 2019 and 2020, respectively.

There is an inherent risk of failure for each of our drug candidates. We cannot predict when or if any of our drug candidates will prove effective and safe for humans or will receive regulatory



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approval. Before obtaining regulatory approval from regulatory authorities for the sale of any drug candidate, our drug candidates must complete pre-clinical studies and we must then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, and can take many years to complete. The outcomes of pre-clinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. For instance, in December 2020, SGX-942, one of our potential drug candidates, failed to achieve its Phase III clinical endpoint. As a result, we provided full impairment to related intangible assets in the amount of RMB21.0 million. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. Since relatively few development programs in the pharmaceutical industry produce a commercially viable product, a product candidate that appears promising in the early phases of development may fail to reach the market for a number of reasons. For example:

- regulators or institutional review boards (“IRBs”), or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us or them, to conduct additional clinical trials, or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may fail to conduct a companion diagnostic test to identify patients who are likely to benefit from our drug candidates;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical development for various reasons, including non-compliance with regulatory requirements, undesirable side effects or unexpected characteristics, or a finding that participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;
- we may fail to obtain approvals for intended indications from relevant regulatory bodies, such as the NMPA, or fail to obtain timely approvals and lose market opportunities;
- we may fail to manufacture and commercialize;
- third parties may hold proprietary rights, such as patent rights related to our product candidate and they may refuse to sell or license such rights to us on reasonable terms or at all, or may include restrictive terms in their license; and
- there may be changes in the applicable regulatory framework, which may make our development process more time-consuming and costly. See “— We are subject to

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changing legal and regulatory requirements in the pharmaceutical industry, and new laws, rules and regulations may adversely affect our operations, revenue and profitability or impose additional compliance burdens on us.”

New pharmaceutical products must be approved by the NMPA before they can be marketed and sold in China. The NMPA requires successful completion of clinical trials and demonstration of manufacturing capabilities before granting approval, and it often takes several years before a medicine can be ultimately approved by the NMPA. In addition, the NMPA and other regulatory authorities may apply more stringent standards in reviewing the applications. For example, in July 2015, the NMPA introduced certain new measures in connection with reviewing IND and NDA applications, which, among others, required that applicants conduct a self-review of clinical trial data of 1,622 listed drugs with pending applications for manufacturing or importation approval to ensure safety and efficacy, and accuracy of clinical trial data pursuant to the Notice in relation to the Self-review of Clinical Trials Data of Pharmaceutical Products (《關於開展藥物臨床試驗數據自查核查工作的公告》). Complying with existing or potential new standards may be time-consuming and expensive and could result in delays or preclude us from obtaining NMPA approval for our product candidates.

Even if we do obtain regulatory approvals, the process may take longer than expected, or such approvals may be subject to limitations on the indicated uses for which we may market the relevant product, thereby restricting its market size, which in turn could adversely affect our operations, revenue and profitability.

**The market opportunities for our drug candidates may be smaller than we anticipate, which could render some drug candidates less profitable than expected even if commercialized, and we may fail to capitalize on drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.**

We estimate the incidence and prevalence of target patient populations for particular diseases based on third-party sources, such as scientific literature, surveys of clinics, patient foundations or market research, as well as internally generated analysis, and we use such estimates in making decisions regarding our drug development strategy, including determining which candidates to focus our limited resources on in pre-clinical or clinical trials. These estimates may be inaccurate or based on imprecise data. The total addressable market opportunity will depend on, among other things, acceptance of the drug by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or access.

Furthermore, new studies may change the estimated incidence or prevalence of these diseases, and the number of addressable patients for our drug candidates in any case may turn out to be lower than expected. In such cases, even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. Any of the above unfavorable developments could have a material adverse effect on our operations, revenue and profitability.

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Because we have limited financial and managerial resources, we must limit our licensing and development programs to specific drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. 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 drug candidate, we may relinquish valuable rights to that drug 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 drug candidate.

**If we fail to attain market acceptance for our proprietary product, in-licensed products or promotion products for business partners among the medical community in China, including existing or future products, our operations, revenue and profitability could be adversely affected.**

The commercial success of our products, including existing or future products, depends on the degree of market acceptance they achieve among the medical community, particularly medical professionals and hospitals. The acceptance of any of our products among the medical community will depend upon several factors, including but not limited to:

- the safety and efficacy of the product;
- the cost of the product;
- the effectiveness of our efforts to market the product to hospitals and medical professionals; and
- the perceived advantages and disadvantages of the product, including the prevalence and severity of side effects, relative to competing products or treatments.

In addition, market acceptance of a product is also affected by whether it is included in the national and provincial medical insurance drug catalogues. See “— If the products we sell are removed or excluded from provincial or other government-sponsored medical insurance programs, patients in certain income classes may not be able to afford our products and our operations, revenue and profitability could be adversely affected.” above.

If our products fail to achieve or maintain widespread market acceptance, or if new products introduced by our competitors are perceived more favorably by healthcare practitioners and patients, are more cost-effective or otherwise render our products obsolete, the demand for our products may decline and our operations, revenue and profitability may be materially and adversely affected.

**We may experience prolonged delay or significant disruption to the supply of promotion products for business partners, or an increase in the purchase prices of such products, which may adversely affect our operations, revenue and profitability.**

We depend on leading multi-national pharmaceutical manufacturers such as Baxter and Pfizer to supply key promotion products for business partners currently in our product portfolio. We may

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experience unexpected interruption in the supply of such products for a number of reasons, such as changes to regulatory requirements, imposition of import restrictions, loss of or failure to renew certifications or licenses, interruptions to or breakdowns in the manufacturing operations of our suppliers, disruptions in logistics or delivery of products to us, natural disasters (including but not limited to flooding, typhoons, earthquakes, blizzards and snow storms), acts of terror or other third-party interference.

In addition, our suppliers may adjust the prices of promotion products for business partners when they renew their supply agreements with us or otherwise in accordance with the terms of the supply agreements, resulting in an increase in our costs. Because of market factors or pricing regulations established by the PRC government, we may be unable to entirely offset increased costs by increasing the prices of our products. Any disruption to the supply of promotion products for business partners, or any increase in the purchase prices of such products, could have a material adverse effect on our operations, revenue and profitability.

**Our sales are concentrated in China and we face risks relating to operating in China, including risks due to changes in the regulatory environment, slow payment cycles and exposure to fluctuations in the Chinese economy.**

A significant portion of our revenue and profit is derived from operations in China. Consequently, our overall financial results are dependent on this market, and our business is exposed to risks there. A downturn in the Chinese economy could materially and adversely affect our revenues and results of operations. In addition to the risks relating to pricing previously discussed above, these risks also include changes in economic conditions (including wage and cost inflation, currency exchange rates, consumer spending and employment levels), tax rates, laws, changes in the regulatory environment, increased competition and potential noncompliance with local laws and regulations. For instance, we are required to make minimum amounts of social insurance and housing provident funds contributions for the benefit of our employees in the manner as requested under PRC laws and regulations, and non-compliance of such requirements may subject us to penalties by the relevant authorities. Furthermore, we have leased properties in China primarily for use as offices and the backup warehouse, and non-compliance with the relevant PRC laws and regulations, such as failure to make the administrative filings of the lease agreements, could subject us to fines and require us to cease occupation and use of the leased properties. Risks also include changing pharmaceutical product preferences and preferred sales channels, as well as our ability to accommodate such changing preferences. Certain risks and uncertainties of doing business in China are solely within the control of the PRC government. Also, any significant or prolonged deterioration in China's relations with the United States and other countries could adversely affect our China business, as we purchase raw materials from overseas partners and produce our products through collaboration with our overseas partners. There are also uncertainties regarding the interpretation and application of laws and regulations and the enforceability of intellectual property and contract rights in China. There can be no assurance as to the future effect of any such risks and uncertainties on our results of operations, revenue or cash flows.

We experience other issues with managing sales operations in China including long payment cycles, potential difficulties in timely accounts receivable collection and, especially from significant

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customers, fluctuations in the timing and amount of orders, and the adverse effect of any of these issues on our business could be increased due to the concentration of our business with a small number of distributors. Problems with collections from, or sales to, any one of those distributors could materially adversely affect our results.

Our future results could be adversely affected by changes in laws and regulations, including, among others, changes in accounting standards, taxation requirements (including tax rate changes, new tax laws and revised tax law and regulatory interpretations), competition laws, privacy laws and environmental laws in China and other countries.

Compliance with changing regulations concerning corporate governance and public disclosure has resulted in and may continue to result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for companies such as ours, and costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment has resulted, and may continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

**We are exposed to concentration risk of reliance on sales through a limited number of distributors. If we are unable to maintain business relationships with our distributors, our operations, revenue and profitability could be adversely affected.**

We sell most of the products through distributors. We rely on sales through distributors for our sales and as a result, our operations, revenue and profitability depend on, among other things, the continuous contribution of sales revenue through distributors and our continuous relationship with them. Our reliance on the limited number of distributors for sales revenue will have significant impact on our operations and revenue if any uncontrollable adverse event happens on these distributors. There is no assurance that they will continue the distribution arrangement with us, whether on similar terms as the existing arrangements or at all, and the termination or unfavorable change in the terms of such arrangements may significantly affect our operations and revenue.

We cannot assure you that our distributors will at all time strictly adhere to the terms and conditions under our distribution arrangements. Any wrongdoing of the distributors or their employees, such as corruption or deliberate contamination of or tampering with our products may harm our operations or give rise to product liability claims or customer complaints against us. If any of our distributors fails to distribute our products in a timely or effective manner or in accordance with the terms of our sales and distribution agreements, or at all, or if our sales and distribution agreements are suspended, terminated or otherwise expired without renewal, our operations, revenue and profitability could be materially and adversely affected.

The distributors may not be able to market and sell our products successfully or maintain their competitiveness as a result of various factors. If the sales volumes of our products are not

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maintained at a satisfactory level, our distributors may not place orders for new products with us, or they may reduce orders or ask for discount on purchase price. The loss of our distributors, reduced orders from them or reduce in sales price, could adversely affect our sales volume and revenue.

If we fail to successfully maintain our relationships with the distributors or our distributors fail to operate successfully, our ability to effectively sell our products could be adversely affected. Accordingly, our corporate and product image may be adversely affected, possibly resulting in decline in sales.

**Our operations, revenue and profitability may be adversely affected by the “two invoice system” if we lose the exclusivity on the promotion products we sell for business partners.**

As one of the measures of the PRC healthcare system reform, the State Council together with seven other central government departments (including the NHC and the NMPA) jointly issued the Notice of Publishing Opinions on Implementing Two-invoice System in Drug Procurement Among Public Medical Institutions (For Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行“兩票制”的實施意見（試行）的通知》) on December 26, 2016. See “Regulatory Overview — Distribution of Drugs — Two-invoice System.”

The “two-invoice system” refers to the system under which the value added invoices are allowed to be issued twice aggregately in the process of the distribution, where one value added invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other value added invoice to be issued from pharmaceutical distributors to medical institutions. The domestic general agent within the territory of the PRC for overseas drugs can be deemed as a pharmaceutical manufacturer under the “two-invoice system”, provided that only one such general agent is permitted within the territory of the PRC.

For the promotion products we sell for business partners, we import and distribute through SciClone Jiangsu. If we lose the exclusivity on the promotion products we sell for business partners, SciClone Jiangsu may no longer be deemed as a pharmaceutical manufacturer for such promotion products under the “two-invoice system”, and we may have to adjust our sales model accordingly as SciClone Jiangsu, being a pharmaceutical distributor, will only be able to issue one invoice to the public hospitals or medical institutions, which could adversely affect our operations, revenue and profitability.

**If counterfeit versions of our proprietary product, in-licensed products or promotion products for business partners become available in the market, our operations, reputation and the brand names for the relevant products could be adversely affected, and we may be exposed to liability claims.**

Certain products distributed or sold in the pharmaceutical markets in the PRC and overseas may be manufactured without proper licenses or approvals or fraudulently mislabeled with respect to their content or manufacturer. These products are generally referred to as counterfeit pharmaceutical

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products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as the PRC, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products, including those imitating the products we sell. Consequently, certain pharmaceutical products sold in the PRC and other markets may be counterfeit products.

Since counterfeit pharmaceutical products are generally sold at lower prices than authentic pharmaceutical products, and are in some cases very similar in appearance to authentic pharmaceutical products, counterfeit products imitating our own pharmaceutical products can quickly erode our sales volume of the relevant product. 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 more likely to 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.

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. We have in the past become aware of some limited instances of counterfeit version of some of our products. Although these instances have not had a material adverse effect on our business and operations, there can be no assurances that instances of counterfeit version of our products in the future will not have a material adverse effect on us or we will be able to prevent future occurrences in the PRC.

In addition, any negative publicity relating to counterfeit products concerning us, any other company in the pharmaceutical industry in China or in general, even if untrue, could adversely affect our reputation and business prospects. We cannot assure you that negative publicity about us would not damage our brand image or have a material adverse effect on our operations, revenue and profitability.

**We cannot predict the safety profile of the use of our proprietary product, in-licensed products or promotion products for business partners, particularly when used in combination with other drugs.**

While the products we sell have good safety profiles, we cannot predict whether any product we sell may have unexpected safety issues in new patient populations or when used in new indications. For instance, the same drug could have different effects on patients with different physical conditions or on other medications, and the corresponding reactions could be unpredictable. In addition, we cannot predict how the products we sell or other drugs we may develop or market will work with other drugs, including causing possible adverse side effects not directly attributable to the other drugs that could compromise the safety profile of the products we sell or other drugs we may develop or market when used in certain combination therapies. We are exploring new indications for the products we sell and there is a risk that new safety issues could appear in these new patient populations.

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As we introduce new products, there may be adverse safety events related to those products. Adverse safety events may have a negative impact on our business. Discovery of safety issues with our products could create product liability and could cause additional regulatory scrutiny and requirements for additional labeling, withdrawal of products from the market, and the imposition of fines or criminal penalties. Adverse safety events may also damage confidence in our products and our reputation. Any of these could result in liabilities, loss of revenue, material write-offs of inventory, material impairments of goodwill and fixed assets, material restructuring charges and other adverse impacts on our operations.

Regulatory authorities are making greater amounts of stand-alone safety information directly available to the public through periodic safety update reports, patient registries and other reporting requirements. The reporting of adverse safety events involving our products or products similar to ours and public rumors about such events may increase claims against us and may also cause our product sales to decline or experience periods of volatility.

**If third-party reimbursement is not available or patients cannot otherwise pay for our proprietary product, in-licensed products or promotion products for business partners, we may not be able to successfully market them.**

Significant uncertainty exists as to the reimbursement status of therapeutic products, such as the products we sell or other drugs we may develop. We cannot assure you that third-party insurance coverage and reimbursement will be available for therapeutic products we might develop. Although certain reimbursement is available in China for the products we sell, we cannot assure you that we will be able to maintain existing reimbursements or increase third-party payments for the products we sell or obtain third-party payments for other products that we sell or develop in China. The failure to maintain third-party reimbursement for our products would harm our business.

Recent efforts by governmental and third-party payers to contain or reduce health care costs and the announcement of legislative proposals and reforms to implement government controls has caused us to reduce the prices at which we market our products in China, and additional reforms, if they were to occur, could cause us to further reduce our prices which could reduce our gross margins and may harm our business.

**We rely on third parties for development, commercialization and other aspects of our business, and the inability of any of these parties to reliably, timely or cost-effectively provide us with their obligated services could materially harm the timing of bringing our products to market and accordingly adversely affect our business.**

We rely on third parties, such as collaboration partners, medical institutions, clinical investigators, and contract laboratories, in the development of our product candidates and in the conduct of clinical trials for our product candidates. We are also dependent upon third parties for the commercialization or distribution of products or product candidates, including our distributor for Angiomax in China and our distributors for Zadaxin in South Korea. If these parties, whom we do not control, do not successfully carry out their contractual duties or regulatory obligations or meet



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expected deadlines, or if our collaboration partners do not have the ability or the resources to successfully complete their objectives, or choose not to continue their relationship with us, our development efforts could be delayed, suspended or terminated, or our commercialization efforts may be delayed, impaired or terminated. If the quality or accuracy of the data they obtain through third parties is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical or clinical activities could be delayed and we may not be able to obtain regulatory approval for our product candidates.

**If our thymalfasin API or Zadaxin products are not shipped and stored at precise temperatures, the products could become damaged, which could negatively affect our sales and operating results.**

Thymalfasin API and Zadaxin are temperature-sensitive products. We rely on third-party organizations to provide temperature-controlled shipping logistics services from the point of ownership transfer from the API contract manufacturer to the point where thymalfasin API is converted to Zadaxin drug product, and from the Zadaxin drug product manufacturing site to China. Although some temperature fluctuations are allowable and thymalfasin and Zadaxin are relatively stable when exposed to temperatures higher than recommended, if any third-party logistics or equipment provider fails to perform its required oversight duties with respect to temperature control or a shipment is delayed in transit for a prolonged period of time, the thymalfasin API or Zadaxin drug product could become unsuitable for subsequent processing or commercial use. Although we have not experienced cold chain interruptions in the past and our distributor in China may maintain several months' supply of our product, were our cold chain distribution or warehouse capability to be interrupted, our ability to timely deliver finished product to China could be adversely affected, which in turn could materially adversely affect our sales and operations.

**We may pursue collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other investments or arrangements. If such arrangements fail to achieve our set goals or produce anticipated benefits, our operations, revenue and profitability could be adversely affected.**

We continually pursue opportunities for collaboration, in-licensing, joint ventures, acquisitions of products, assets or technologies, strategic alliances, or partnerships that we believe would be complementary to or promote our existing business. Proposing, negotiating and implementing these opportunities 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 be able to identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all.

Management and integration of a licensing arrangement, collaboration, joint venture or other strategic arrangements may disrupt our current operations, decrease our profitability, result in significant expenses, or divert management resources that otherwise would be available for our existing business. We may not realize the anticipated benefits of any such transaction or arrangement.

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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 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 actions, consents, approvals, waivers, participation or involvement in various degrees by 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, consents, approvals, waivers, participation or involvement on a timely basis, on acceptable terms, or at all.

### **We may not be able to successfully license-in new drug candidates.**

We seek to license-in promising drugs or drug candidates to expand our existing portfolio. We cannot assure you that if we decide to license-in other drug candidates in the future, we will be successful in identifying favorable candidates or that the prospective licensor would agree to license such products to us at favorable commercial terms or at all. Even if we are able to license-in the drugs or drug candidates that we target, we cannot assure you that the products will be successfully commercialized.

Even after we successfully license-in drug candidates, we cannot assure you that our licensors will not breach the relevant license agreements, whether inadvertently or otherwise. Alternatively, our licensors might conclude that we have materially breached our license agreements. In either case, the license agreements may be terminated, thereby removing our ability to develop and commercialize the drug candidates we licensed-in.

### **If we are unable to conduct effective promotion or maintain a qualified sales force, the sales volume of our proprietary product, in-licensed products and promotion products for business partners and our operations, revenue, profitability and business prospects could be adversely affected.**

Successful sales and marketing are crucial for us to increase the market penetration of our existing products, expand our coverage of hospitals and other medical institutions and promote new products in the future. If we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities, our sales volumes and business prospects could be adversely affected.

In particular, our sales and marketing efforts consist of raising awareness and knowledge of our products and product candidates among medical professionals, hospitals and other medical institutions throughout China. Therefore, our sales and marketing force must possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication

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skills. If we are unable to effectively train our in-house sales representatives and evaluate their academic marketing performance, our sales and marketing may be less successful than desired. See “Business — Sales, Marketing and Distribution.”

Moreover, our ability to attract, motivate and retain a sufficient number of qualified sales professionals is especially important because we primarily rely on our in-house sales force to market and sell our products. Competition for experienced marketing, promotion and sales personnel is intense. If we are unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals, sales volume of our products may be adversely affected and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

**If we fail to maintain, expand and optimize an effective distribution network for our proprietary product, in-licensed products and promotion products for business partners or encounter problems with our distributors, our operations, revenue and profitability could be adversely affected.**

Our ability to maintain and expand our business and satisfy the demand for our drugs will depend on our ability to maintain, expand and optimize a distribution network that timely delivers our products throughout China where we generate market demand through our sales and marketing activity, or otherwise. However, our distributors are all third parties over whom we have limited control. Our distributors may not distribute our pharmaceutical products in the manner we contemplate, which may impair the effectiveness of our distribution network. Since our distributors do not sell our products on an exclusive basis, our products also compete with similar products from our competitors sold by our distributors.

We typically enter into agreements with our distributors for a prescribed term. See “Business — Sales, Marketing and Distribution.” Our distributors might elect not to renew their agreements with us or otherwise terminate their business relationships with us for reasons including in the event that PRC pricing regulations or other factors limit the margins our distributors can obtain through the resale of our pharmaceutical products to pharmacies, hospitals and other medical institutions. Our strategies contemplate expansion of our sales and distribution network by increasing our presence in county-level and community hospitals. We may not be able to establish relationships on commercially acceptable terms with new distributors to cover these areas. In the event that a significant number of our distributors terminate their relationships with us, or we are otherwise unable to maintain and expand our distribution network effectively, our sales volumes and business prospects could be adversely affected. Additionally, in the event that a significant number of our distributors cease or reduce their purchases of our products or fail to meet the terms of our distribution agreements, our operations, revenue and profitability may be materially and adversely affected. See “Business — Sales, Marketing and Distribution — Distribution in China.”

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**If we or parties on whom we rely fail to maintain the necessary licenses for the development, production, promotion, sales and distribution of our proprietary product, in-licensed products or promotion products for business partners, our ability to conduct our business could be materially impaired and our operations, revenue and profitability could be adversely affected.**

We are required to obtain, maintain and renew various permits, licenses, approvals and certificates in order to develop, produce, promote and sell our pharmaceutical products, and the third parties on whom we may rely to develop, produce, promote, sell and distribute our products may be subject to similar requirements. See “Business — Legal and Compliance — Licenses and Permits.” We and the parties on whom we rely, such as distributors and suppliers, may be subject to regular inspections, examinations, inquiries and audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries and audits may result in the loss or non-renewal of the relevant permits, licenses, approvals and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses, approvals and certificates may change from time to time, and there can be no assurance we or the parties on whom we rely will be able to meet new criteria that may be imposed in order to obtain or renew the necessary permits, licenses, approvals and certificates. Many of such permits, licenses, approvals 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, approvals and certificates, it could materially impair our ability to conduct our business. While we have always been able to maintain and renew our material permits, licenses, approvals and certificates, there is no assurance that we will be able to continue doing so in the future.

Any changes in the standards used by governmental authorities in considering whether to renew or reassess our licenses, permits, approvals and certificates, as well as any enactment of new regulations that may restrict the conduct of our business, may also decrease our revenue and increase our costs, which in turn could materially and adversely affect our profitability and prospects. Furthermore, if the interpretation or implementation of existing laws and regulations changes, or new regulations come into effect, so as to require us or parties upon whom we rely to obtain any additional permits, licenses, approvals or certificates that were previously not required to operate our business, there can be no assurances that we or parties upon whom we rely will successfully obtain such permits, licenses, approvals or certificates.

**If we fail to maintain optimal inventory levels, our operating costs could be increased and our customer orders may be unfulfilled, and our operations, revenue, profitability and business prospects could be adversely affected.**

We are required to maintain optimal 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 rapid changes in product life cycles, changing clinical demands, uncertainty of product developments and launches 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. 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

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accurately. See “Business — Production and Quality Control — Quality Management — Inventory Management.”

We have an extensive product portfolio and maintain certain inventory levels for a substantial portion of our products for sales into our distribution network. We may be unable to sell such inventory in sufficient quantities. Inventory levels in excess of demand may result in inventory write-downs, expiration of our products 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 any such failure may have a material and adverse effect on our business, financial condition, results of operations and prospects.

**Our business depends on our key senior management members, key development personnel and key marketing and sales personnel. If we are unable to retain our key employees, or are unable to attract and retain skilled and experienced personnel, our ability to conduct our business could be materially impaired and our business prospects could be adversely affected.**

Our success depends heavily upon the continued services of our key senior management personnel, key development personnel and key sales and marketing personnel. In particular, the industry experience, management expertise and contributions of the members of our senior management are crucial to our success. Our development team is critical to the development and commercialization of our products and realization of the potential benefits of our intellectual property. In addition, success in the pharmaceutical distribution and pharmaceutical retail of our products depends on the dedication and skills of our sales and marketing personnel. Accordingly, our ability to attract and retain key personnel is a critical factor in our competitiveness. If we lose the services of any key personnel, we may be unable to recruit a suitable or qualified replacement and may incur additional expense to recruit and train new personnel, which could disrupt our business and growth. Furthermore, as we expect to continue expanding our operations and product portfolio, we will need to continue attracting and retaining experienced management personnel with extensive managerial, technical, development or sales and marketing experience. Competition for these individuals in the pharmaceutical industry is intense, and the availability of suitable and qualified candidates in China is limited. Competition for these individuals could cause us to offer higher compensation and other benefits in order to attract and retain them, and consequently increase our operating costs and in turn, materially and adversely affect our operations, revenue and profitability. We may be unable to retain these key personnel required to achieve our business objectives, and failure to do so could adversely affect our business prospects.

**If we experience delays in collecting payment from distributors, our operations and cash flow could be adversely affected.**

We generally grant our distributors credit terms of 45 to 90 days. As of September 30, 2020, we had trade receivables of RMB410.1 million. If our distributors’ cash flow, working capital, financial

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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 flow, and we could be required to terminate our relationships with distributors in a manner that impairs the effective distribution of our pharmaceutical products.

**If our proprietary product, in-licensed products or promotion products for business partners cause, or are perceived to cause, severe side effects, our operations, revenue, profitability and business prospects could be adversely affected.**

The products we sell may cause severe side effects as a result of a number of factors, many of which are outside of 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.

In addition, 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 the NMPA or other regulatory agencies, determines that products containing the same or similar pharmaceutical ingredients as our products could cause or lead to severe side effects.

**We may be subject to product liability lawsuits, and our insurance may be inadequate to cover damages.**

We are exposed to product liability risks as a result of developing, producing, marketing, promoting and selling pharmaceutical products in the PRC and other jurisdictions in which our pharmaceutical products are marketed and sold. 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 insufficient or improper labeling of products or providing inadequate warnings or insufficient or misleading disclosures of side effects. There can be no assurance 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, strain our financial resources and consume the time and attention of our management, which might incur substantial costs and lead to diversion of resources. It may also result in damage to our reputation, product recalls and loss of our revenue and capabilities 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 pharmaceutical products are found to be defective. In addition, we may be required to recall the relevant pharmaceutical products, suspend sales or cease

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sales. Other jurisdictions in which our products are, or may in the future be, sold, in particular in more developed markets including the U.S., may have similar or more onerous product liability and pharmaceutical product regulatory regimes, as well as more litigious environments that may further expose us to the risk of product liability claims. Our product liability insurance to cover damages that may arise from product liability claims may be inadequate. 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. During the Track Record Period and as of the Latest Practicable Date, there had been no product liability claim brought by third parties against us.

PRC laws and regulations currently do not require us to maintain liability insurance to cover product liability claims. We currently maintain insurance for bodily injury and property damage arising out of the products we sell, adverse effects in clinical trials, and shipment of our cargos, and such insurance may not fully cover our potential liabilities. We currently do not intend to purchase insurance covering other aspects of risks. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we develop.

**If we are unable to adequately protect our intellectual property, or if the scope of our intellectual property fails to sufficiently protect our proprietary rights, other pharmaceutical companies could compete against us more directly, and our operations, revenue and profitability could be adversely affected.**

Our commercial success depends in part on our ability to protect our existing intellectual property and to obtain additional patents or other intellectual property, in particular to protect our products from direct substitute products. See “Business — Our Products and Services” and Appendix V to this prospectus for further details of our material intellectual property including patents and copyrights.

If we do not adequately protect our intellectual property, competitors may be able to imitate or copy our products, use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. Furthermore, the process of seeking patent protection in the PRC can be lengthy and expensive and there is no assurance that any of our pending patent applications will mature into issued patents, or that such patents, if issued, will provide us with adequate proprietary protection or competitive advantages. The scope of protection for issued patents may also vary across different jurisdictions. The PRC has adopted a first to file system for patent applications, meaning whoever files an application for the same invention first will be awarded the patent. As a result, a third party may be granted a patent relating to a technology we believe we invented.

There are a number of factors that could cause our existing patents or other intellectual property to become invalid or unenforceable, including known or unknown prior art, deficiencies in patent applications and lack of originality in the underlying technologies. Certain of our patented technologies are utilized in a number of our products and product candidates and if the patents relevant to these technologies were to be declared invalid or unenforceable, it could have an adverse

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impact on the sales volumes and pricing levels for such products and our ability to successfully commercialize such product candidates.

In addition, the patents and patent applications for our current products, as well as a substantial portion of the product candidates we intend to develop, generally relate to the compositions including NMEs, delivery systems, preparation methods, production processes, or formulation of the relevant products and do not cover the active, underlying pharmaceutical ingredients. Therefore, such patents may be insufficient to protect us from the development of substitute products by competitors, who may be able to do so by designing around our products using the same active pharmaceutical ingredients. In addition, patents covering preparation methods and formulation may not create sufficient technical barriers to prevent other drug developers from developing substitute products.

Furthermore, the patents that we hold, including the patents for each of our key products, are for a finite duration. Following the expiration of the relevant patents, our existing or future competitors may be able to develop and introduce direct substitute products to our key products which may be identical in formulation. In the event that our competitors introduce direct substitutes for these products, it could have an adverse impact on the sales volumes and pricing levels for such products.

Moreover, intellectual property rights protection in China may not be as effective as in developed countries. Detecting and policing unauthorized use of proprietary technology are difficult and expensive. We may need to resort to litigation to enforce or defend patents issued to us or determine the enforceability, scope and validity of our proprietary rights or those of others. An adverse determination in any such litigation could materially impair our intellectual property rights. If our intellectual property rights are inadequate as a result of the narrow scope of the patents granted or third parties' infringement, or we otherwise fail to sufficiently protect our intellectual property, our business, financial condition and results of operations could be adversely affected.

**We may be subject to intellectual property infringement claims, which could expose us to substantial liability, adversely affect our reputation and limit our development or other business activities and/or our ability to commercialize our drug candidates.**

Our success depends significantly on our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. In the PRC, invention patent applications are generally maintained in confidence until their publication 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 invention patent applications are filed. Even after reasonable investigation, we may not know with certainty whether any third-party may have filed a patent application without our knowledge while we are still developing or producing that product. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any drug candidates we may develop.



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Third parties may assert infringement claims against us based on patents or other proprietary rights that we currently hold or may be granted in the future, regardless of their merit. We may receive in the future notices that claim our technologies or certain other aspects of our business have infringed, misappropriated or misused other parties' intellectual property rights. Whether or not third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any drug candidates we may develop and any other drug candidates or technologies covered by the asserted third-party patents.

If we are found to infringe on a third party's intellectual properties, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to:

- obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, or at all and even if we were able to obtain such licenses, they could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing and royalty payments;
- defend litigation or administrative proceedings;
- reformulate our product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be costly and time consuming;
- cease developing, manufacturing and commercializing the infringing technology or drug candidates; and
- pay such third party significant monetary damages, if we are found to have willfully infringed a patent or other intellectual property right.

Some 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 development programs, in-license needed technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a material adverse effect on our business, financial condition, results of operations, and prospects. Even if we are successful in litigation or administrative proceedings, such litigation and proceedings may be costly and could result in a substantial diversion of management resources. Any of the foregoing may have a material adverse effect on our business, prospects, financial condition and results of operations. During the Track Record Period and as of the Latest Practicable Date, there had been no intellectual property related claims brought by third parties against us.

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**If we or our brand names fail to maintain a positive reputation, our operations, revenue and profitability could be adversely affected.**

We depend on our reputation and the brand names of our products in many aspects of our business, including but not limited to:

- to gain access to, and for our products to be perceived favorably by, hospitals and medical professionals that drive and affect patient demand for pharmaceutical products;
- to effectively work with the relevant authorities that regulate various aspects of our business;
- to gain the trust of patients and consumers of our products;
- to competitively position ourselves in the centralized tender process required for our pharmaceutical products to be sold to public hospitals and medical institutions in the PRC;
- to successfully attract employees, distributors, and other partners to work with us; and
- to increase market share of our products through brand recognition.

However, there can be no assurance that we will be able to maintain a positive reputation or brand name for all our products in the future. Our reputation and the brand names of our products may be adversely affected by a number of factors, many of which are outside our control, including but not limited to:

- adverse associations with our products, including with respect to their efficacy or side effects;
- the effects of counterfeit products purporting to be our products;
- lawsuits and regulatory investigations against us or otherwise relating to our products or industry;
- improper or illegal conduct by our employees, distributors and suppliers, whether or not authorized by us; and
- adverse publicity that is associated with us, our products or our industry, whether founded or unfounded.

If we or the brand names of our products fail to maintain a positive reputation as a result of these or other factors, our products may be perceived unfavorably by hospitals, medical professionals, regulators and patients, and our operations and business prospects could be adversely affected.

In addition, despite our internal guidelines and supervision efforts, our employees or distributors may fail to follow such guidelines, which may adversely affect our sales and reputation. For example, our employees or distributors may fail to provide accurate and complete information about our products, as a result of which hospitals, medical institutions, doctors and patients may misunderstand or misuse our products. During the Track Record Period and as of the Latest Practicable Date, there had been no such incident to the best of our knowledge. Such misunderstanding or misuse could result in our products being less effective, or cause severe adverse effects that could otherwise be avoided. As a result, the sales volume and reputation of our products could be adversely affected and we could be exposed to product liability lawsuits or regulatory investigations, resulting in penalties, fines or other disruptions to our operations.

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**If we are unable to comply with environmental and other laws and regulations, our business may be harmed.**

We are subject to laws, regulations and recommendations relating to the use, manufacture, storage, handling and disposal of hazardous materials and waste products (including radioactive compounds and infectious disease agents), as well as safe working conditions, laboratory and manufacturing practices and the experimental use of animals. The extent of government regulation that might result from future legislation or administrative action in these areas cannot be accurately predicted.

We do not currently maintain hazardous materials at our facilities. While we outsource our development programs involving the controlled use of biohazardous materials, if in the future we conduct these programs ourselves, we might be required to incur significant cost to comply with environmental laws and regulations. Further, in the event of an accident, we would be liable for any damages that result, and the liability could exceed our resources.

**We may fail to sufficiently and promptly respond to rapid scientific and technological changes, clinical demands and market changes in the pharmaceutical industry, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons.**

The PRC pharmaceutical industry is characterized by rapid advances in science and technology and the continuous emergence of new treatment options. Our future success depends on our ability to launch new products that meet evolving market demands, in particular, new drugs, that are effective in treating and/or diagnosing new diseases and illnesses. We cannot assure you that we will be able to respond to emerging or evolving trends by improving our product portfolio and services in a timely manner, or at all.

In addition, 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 development plan, production scale and schedule, product portfolio, and inventory levels based on customer demand, sales trends and other market conditions. There can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in the future, and such failure may have a material and adverse effect on our operations, revenue and profitability.

The pharmaceutical industry is highly competitive and fragmented. We face competition from both domestic and international competitors across most of our product lines based on quality, the timing and scope of the regulatory approvals, prices, sales and marketing capabilities, the availability and cost of supply, patent position and other factors. In general, we face pricing competition from domestic competitors, and competition on product quality and brand recognition from international competitors. In particular, some of our domestic competitors may have, among other things, greater pricing flexibility and more robust sales networks, which may enable them to offer products with similar functions but lower prices to the end users. We may not be able to

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successfully compete with our competitors and cannot ensure you that we will be able to demonstrate compelling advantages in quality to overcome price competition and to be commercially successful.

In addition, some of our competitors may have, among other things:

- greater financial and other resources;
- a greater variety of products;
- brands and products that are better recognized by doctors who recommend products to patients;
- more extensive development and technical capabilities and human resources;
- stronger manufacturing capabilities; or
- more extensive sales networks.

**Our operations are dependent on the supply of certain raw materials. If the supply of raw materials decreases or the cost increases, our ability to conduct our business could be materially impaired and our operations, revenue and profitability could be adversely affected.**

In order to manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. We sourced active pharmaceutical ingredients and other raw materials used to produce our final products from independent third parties. See “Business — Production and Quality Control — Supply of Raw Materials and Products.” For instance, we rely on third party suppliers to provide us with the active pharmaceutical ingredient for Zadaxin. Should any of our suppliers fail to supply sufficient quantities of raw materials of an acceptable quality in the future, we may be unable to obtain substitute raw materials elsewhere in a timely manner, or at all. We may also be forced to obtain raw materials from different suppliers, who may require us to pay prices that are not commercially reasonable or may provide us with raw materials that are not of an acceptable quality. Although we have not experienced interruptions in our raw material supplies in the past, any potential interruption in our supply of raw materials could delay the production and delivery schedules of the relevant products, which may result in the loss of customers and revenue. In addition, the market prices of raw materials may be subject to significant fluctuations due to various factors. We cannot assure you that we would be able to pass on any increase in raw material costs to our customers, and any substantial fluctuation in market prices of raw materials may materially increase our costs and impact our profitability.

**Our international business is subject to risks and uncertainties associated with different regulatory regimes and reliance on overseas partners.**

We sell our products to certain overseas markets through our overseas partners. However, our presence in overseas markets may expose us to risks and uncertainties, including but not limited to:

- risks associated with dealing with regulatory regimes, regulatory bodies and government policies with which we may be unfamiliar, which may differ materially from those in the PRC, in order to obtain overseas permits, licenses and approvals necessary to manufacture or import, market and sell products in or to overseas jurisdictions;

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- risks associated with commercializing our products in new markets where we have limited experience with the local market dynamics and no existing or developed sales, distribution and marketing infrastructure;
- risks associated with higher costs for new product development and relying on potential overseas partners and/or their distribution network for the development, commercialization, marketing and distribution of our products; and
- increased risk of product liability litigation and regulatory scrutiny arising from the marketing and sale of pharmaceutical products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities.

**The IRS may assert that we are to be treated as a U.S. domestic corporation or otherwise subject to certain adverse consequences for U.S. federal income tax purposes.**

Although we are a limited company incorporated in the Cayman Islands, the U.S. Internal Revenue Service (the “IRS”) may assert that, as a result of certain recent reorganization transactions undertaken by our predecessor corporation, we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes pursuant to section 7874 of the U.S. Internal Revenue Code of 1986, as amended (“Section 7874”). These rules are known as the corporate inversion rules.

Section 7874 generally provides that if, following a direct or indirect acquisition of substantially all of the assets of a U.S. corporation by a non-U.S. corporation, at least 80% of the acquiring non-U.S. corporation’s stock (by vote or value) is considered to be held by former shareholders of the U.S. corporation by reason of holding stock of such U.S. corporation (such test referred to as the “80% ownership test”), then the non-U.S. corporation generally would be treated as a U.S. corporation for U.S. federal income tax purposes even though it is a corporation created and organized outside the U.S.

Based on currently available information, we do not believe that we would be treated as a U.S. corporation under the 80% ownership test, although this conclusion is not free from doubt because neither we nor our reporting accountant, PricewaterhouseCoopers, have completed a detailed analysis of the potential application of the 80% ownership test to us, and our legal advisors have not expressed an opinion with respect to the potential application of Section 7874. If we were treated as a U.S. corporation for U.S. federal income tax purposes under the 80% ownership test, we could be liable for substantial additional U.S. federal income tax on our operations and income. Additionally, if we were treated as a U.S. corporation for U.S. federal income tax purposes, non-U.S. shareholders generally would be subject to U.S. withholding tax on the gross amount of any dividends we pay to such shareholders. There can be no assurance that the IRS will agree with the position that we would not be treated as a U.S. corporation under the 80% ownership test.

The remainder of this prospectus assumes that we will not be treated as a U.S. corporation for U.S. federal income tax purposes. You should consult your own tax advisors regarding the potential consequences of us being treated as a U.S. corporation under the 80% ownership test of Section 7874.

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**We may need to obtain additional funding to support our long-term product development, including funding of in-licensed products, and commercialization programs.**

The implementation of many aspects of our strategies will require significant funding, including, but not limited to:

- the expenses associated with expanding our sales and distribution network;
- the costs of drug development programs for the expansion of our product portfolio;
- the costs of in-licensed intellectual properties for the development of new products; and
- the funding required to consummate acquisitions.

In addition, many aspects of our general business operations have ongoing funding requirements that may increase over time.

Over the longer term, we expect that the implementation of our strategies and business plans may require us to rely in part on external financing sources. However, our ability to obtain external financing on commercially reasonable terms, or at all, will depend on a number of factors, many of which are outside of our control, including our revenue, profitability and cash flows, China's economic condition, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. If we cannot obtain sufficient external funding on commercially acceptable terms, or at all, 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.

**The discontinuation of any of the financial incentives currently available to us could adversely affect our operations, revenue and profitability.**

The current or future preferential tax treatments, tax concessions, tax allowances and financial incentives applicable to our Company or our subsidiaries may be changed, terminated, or otherwise become unavailable due to many factors, including changes in government policy or administrative decisions by relevant government authorities. For example, on November 27, 2014, the State Council issued the Notice on Cleaning Up and Regulating Taxation and Other Preferential Policies (《國務院關於清理規範稅收等優惠政策的通知》) (the “**Preferential Policies Notice**”), which required local governments and government agencies to review and clean up the preferential policies they have promulgated, and to abolish preferential policies that are in violation of state laws and regulations. On May 10, 2015, the State Council issued a notice suspending the clean-up of preferential policies set out in the Preferential Policies Notice until further notice. We recorded government grants income in the amounts of RMB7.3 million, RMB8.3 million, RMB6.8 million, RMB6.8 million and RMB9.8 million in 2017, 2018, 2019 and the nine months ended September 30, 2019 and 2020, respectively. Due to the Preferential Policies Notice and further potential changes in government policies, we cannot be certain of the level of government grants we will receive in the future. Our post-tax profitability and cash flows may be adversely affected as a result of one or more of these or other factors.

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**The determination of the fair value changes and impairment of certain of our assets requires the use of estimates that are based on unobservable inputs, and therefore inherently involves a certain degree of uncertainty, which may significantly affect our financial position and results of operations.**

We use significant unobservable inputs, such as expected volatility, discount for lack of marketability, risk-free interest rate, expected rate of return and discount rate, in valuing certain of our assets, including financial assets at fair value through profit or loss and financial assets at fair value through other comprehensive income. As of September 30, 2020, we had financial assets at fair value through profit or loss of RMB125.3 million and financial assets at fair value through other comprehensive income of RMB166.0 million. The fair value changes of financial assets at fair value through profit or loss and financial assets at fair value through other comprehensive income may significantly affect our financial position and results of operations. Accordingly, such determination requires us to make significant estimates, which may be subject to material changes, and therefore inherently involves a certain degree of uncertainty. Factors beyond our control can significantly influence and cause adverse changes to the estimates we use and thereby affect the fair value of such assets and liabilities. These factors include, but are not limited to, general economic condition, changes in market interest rates and stability of the capital markets. Any of these factors, as well as others, could cause our estimates to vary from actual results, which could materially and adversely affect our results of operations and financial condition. In addition, the process for determining whether an impairment of financial asset is other-than-temporary usually requires complex and subjective judgments, which could subsequently prove to have been wrong.

**We recorded significant amount of intangible assets and our operating results may vary significantly due to the impairment of such assets.**

As of September 30, 2020, we had intangible assets of RMB567.9 million. Intangible assets represented a significant portion of the assets on our consolidated balance sheet as of September 30, 2020. The value of intangible assets is based on a number of assumptions made by the management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant write-off of our intangible assets and record a significant impairment loss, which could in turn adversely affect our results of operations. For instance, in December 2020, SGX-942, one of our potential drug candidates, failed to achieve its Phase III clinical endpoint. As a result, we provided full impairment to related intangible assets in the amount of RMB21.0 million. Intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. As a result of such tests, we could be required to book impairment charges in our statement of profit or loss. The amount of any potential impairment is not predictable. Any significant impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information regarding our impairment policy in relation to intangible assets, see “Financial Information — Certain Balance Sheet Items — Intangible Assets — Impairment Test” and Note 19 to the Accountant’s Report included in Appendix I to this prospectus.

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### **We are subject to risks relating to fluctuations in foreign exchange rates.**

We are exposed to foreign exchange risk primarily through sales and purchases, capital expenditures and expenses that are denominated in a currency other than Renminbi. In addition, we are also subject to currency conversion risks as our consolidated financial statements are denominated in Renminbi while the financial statements of our subsidiaries are measured and presented in the currency of the primary economic environment in which the entity operates. In 2017 and the nine months ended September 30, 2020, we incurred a net foreign exchange gain of RMB25.8 million and RMB4.5 million, respectively. In 2018 and 2019 and the nine months ended September 30, 2019, we incurred a net foreign exchange loss of RMB35.7 million, RMB10.9 million and RMB20.8 million, respectively. In 2017, we recognized other comprehensive loss through currency translation differences of RMB72.9 million. In 2018 and 2019 and the nine months ended September 30, 2019 and 2020, we recognized other comprehensive income through currency translation differences of RMB57.5 million, RMB27.6 million, RMB47.1 million and RMB22.7 million, respectively. Our foreign currency exposure mainly arises from the exposure of Renminbi against the U.S. dollar.

### **We may grow our business through acquisitions in the future. If we fail to identify quality targets or achieve set goals for the acquisitions, our business prospects could be adversely affected.**

We may in the future accelerate our business growth by taking advantage of consolidation opportunities in the fragmented PRC pharmaceutical industry through selective acquisitions of suitable pharmaceutical companies. However, our ability to successfully complete and realize the intended benefits of any acquisition is subject to a number of risks and uncertainties, including but not limited to:

- we may not be able to identify suitable acquisition targets or have to engage in intense competition for attractive acquisition targets, which may make it difficult to consummate acquisitions on commercially acceptable terms or at all;
- we may not have access to financing for acquisitions on acceptable terms or at all;
- we may fail to obtain or secure governmental approvals and third party consents necessary to consummate any proposed acquisition which may result in liabilities, fines or penalties arising directly from such inability;
- we may have to manage a larger, growing business, operating in new geographical regions and optimizing the allocation of resources and operational efficiency;
- we may fail to effectively integrate development functions; and
- we may fail to retain the management team or development professionals of the acquired businesses.

The PRC regulations and rules concerning mergers and acquisitions, including the M&A Rules promulgated by the CSRC, the SAFE, the MOFCOM and three other PRC governmental and regulatory agencies promulgated on August 8, 2006 and amended on and effective since June 22, 2009, and other recently adopted regulations and rules concerning mergers and acquisitions established a series of procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex,



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including requirements in some instances that the MOFCOM be notified in advance of certain change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise. Moreover, the Anti-Monopoly Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by the NPC in September 1993 and amended on April 23, 2019 requires that the MOFCOM shall be reported to in advance of any concentration of undertaking if certain thresholds are triggered. In addition, the Provisions of Ministry of Commerce on Implementation of Security Review System for Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《商務部實施外國投資者併購境內企業安全審查制度的規定》) (the “**Implementation Provision of Security Review System**”) promulgated by the MOFCOM that became effective in September 2011 specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire *de facto* control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the Implementation Provision of Security Review System prohibits any activities attempting to bypass a security review, including by structuring the transaction through a proxy or contractual control arrangement. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain our market share.

Moreover, the process of seeking and consummating acquisitions, whether successful or not, may divert our resources and management attention from our existing businesses and impair our ability to successfully manage and grow our business organically.

### **Our historical growth may not be indicative of our future performance.**

Our historical growth rate and results may not be indicative of our future growth or performance. There is inherent risk in using our Historical Financial Information to project or estimate our financial performance in the future, as it only reflects our past performance under particular conditions. We may not be able to sustain our historical growth rate, revenue, gross profit margin and return on net assets for reasons including, but not limited to, deterioration in the market conditions of the pharmaceutical industry in China, and outbreak or containment of epidemics, such as COVID-19. For instance, our revenue from the sales of Zadaxin increased significantly in the first half of 2020, as Zadaxin had been used for the prevention and clinical treatment of COVID-19 in China. Such significant increase was a one-off event, and the demand for Zadaxin for the treatment of COVID-19 decreased significantly in the second half of 2020 and may experience a further drop in the future.

In addition, our financial and operating results may not meet the expectations of public market analysts or investors, which could cause the future price of the shares to decline. Our revenue, expenses and operating results may vary from period to period due to a variety of factors beyond our control. As a result of these and other factors, there can be no assurance that our future revenues will increase or that we will continue to be profitable. Accordingly, investors should not rely on our historical results as an indication of our future financial or operating performance.

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**If our internal risk management and control system is not adequate or effective, or if it fails to detect potential risks in our business as intended, our operations, revenue and profitability could be adversely affected.**

As of the Latest Practicable Date, we have an internal control system in place to monitor and control potential risk areas relevant to our business operations. In connection with the Global Offering, 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 Global Offering. 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 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 operations, revenue and profitability 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 operations, revenue and profitability could be materially and adversely affected, particularly with respect to the maintenance of our relevant approvals and licenses granted by the relevant authorities.

**If we, our management or directors become party to litigation, legal disputes, claims or administrative proceedings, our management's or directors' attention may be diverted and our operations, reputation, revenue and profitability could be adversely affected.**

We, our management or directors may from time to time become party to litigation, legal disputes, claims or administrative proceedings arising in the ordinary course of our business. Involvement in litigation, legal disputes, claims or administrative proceedings may distract our management's or directors' attention and consume our time and other resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate due to the various factors involved, such as the facts and circumstances of the cases, the likelihood of winning or losing, the monetary amount at stake and the parties concerned, and such factors may result in these cases becoming of material importance to us.

In addition, negative publicity arising from litigation, legal disputes, claims or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us, we could be required to pay significant

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monetary damages, assume other liabilities, and suspend or terminate the related business ventures or projects. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

**We may experience failures in our information and data management systems and security breaches and other disruptions could compromise our information and expose us to liability, which could adversely affect our operations, revenue and profitability.**

We make use of information and data management systems to obtain, process, analyze and manage data. We use these systems to, among other things, monitor the daily operations of our business, maintain operating and financial data, manage our distribution network as well as manage our production operations and quality control systems. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations. There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner to avoid disrupting our business. The occurrence of any of these events could adversely affect our ability to effectively manage our business operations. In addition, if the capacity of our information systems fails to meet the increasing needs of our expanding operations, our ability to expand may be constrained.

**An occurrence of natural disaster, widespread health epidemic or other outbreaks could adversely affect our operations, revenue and profitability.**

Our business could be materially and adversely affected by natural disasters, such as snowstorms, earthquakes, fires or floods, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome (“SARS”), Ebola, Zika, COVID-19 or other events, such as wars, acts of terrorism, environmental accidents, power shortage or communication interruptions. The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in China or elsewhere in the world could materially disrupt our business and operations. For example, the recent outbreak of COVID-19 has sickened and killed many people in and outside of China, caused temporary suspension of productions and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused and may continue to cause an adverse and prolonged impact on the economy and social conditions in the affected countries. The production and delivery of raw materials and products could be substantially impacted. The commencement of new clinical trials could be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our trials as a result of the outbreak of COVID-19. These factors could cause delay in delivery of products, clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. See “Business — Internal Control and Risk Management — Risk Management in Response to the COVID-19 Outbreak.”

These events could also significantly impact our industry and cause a temporary suspension or closure of the facilities we use for our operations, which would severely disrupt our operations and

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have a material adverse effect on our business, financial condition and results of operations. Our operations could be disrupted if any of our employees or employees of our business partners were suspected of contracting an epidemic disease, since this could require us or our business partners to quarantine some or all of these employees or disinfect the facilities used for our operations. In addition, our revenue and profitability could be materially reduced to the extent that a natural disaster, health epidemic or other outbreak harms the PRC and global economy in general. Our operations could also be severely disrupted if our patients were affected by natural disasters, health epidemics or other outbreaks.

### **RISKS RELATING TO CONDUCTING OPERATIONS IN THE PRC**

**Adverse changes in political, economic and other policies of the PRC government could have a material adverse effect on the overall economic growth of China, which could reduce the demand for our products and adversely affect our operations, revenue and profitability.**

Most of our operations are located in China, and most of our sales are made in China. Accordingly, our business, financial condition, results of operations and prospects are significantly affected by economic, political and legal developments in China.

The Chinese economy differs from the economies of most developed countries in many respects, including, but not limited to:

- the extent of government involvement;
- the level of development;
- the growth rate;
- the control of foreign exchange;
- the allocation of resources;
- an evolving regulatory system; and
- the level of transparency in the regulatory process.

Although China has experienced rapid economic growth over the past decades, its continued growth has slowed since the second half of 2008 and its annual GDP growth rate has declined from 6.9% in 2015 to 6.7% in 2016, 6.9% in 2017, 6.4% in 2018 and 6.1% in 2019. There is no assurance that future growth will be sustained at similar rates or at all.

The PRC government implements various measures intended to encourage economic growth and guide the allocation of resources. These measures may include differential policies towards specific groups of pharmaceutical companies, such as promotion of traditional medicines or state-owned companies, or investments in pharmaceutical companies competing with us, which may have an adverse effect on us. Our operations, revenue and profitability may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us. Further, any adverse change in the economic conditions or government policies in China could have a material adverse effect on overall economic growth and the level of healthcare investments and expenditures in China, which in turn could lead to a reduction in demand for our products and consequently have a material adverse effect on our business.

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The Chinese economy has been transitioning from a planned economy to a more market-oriented economy. Although the PRC government has implemented reform measures allowing for an increasingly market-based economy, reduced state ownership of productive assets and established sound corporate governance practices in business enterprises, a substantial portion of the productive assets in China is owned by the PRC government. The continued control of these assets and other aspects of the national economy by the PRC government could materially and adversely affect our business. The PRC government also exercises significant control over Chinese economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

Changes and developments in China's economic, political and social conditions could adversely affect our operations and revenue. For example, the pharmaceutical market may grow at a slower pace than expected, which could adversely affect our operations, revenue and profitability.

**Our operations are subject to the uncertainties and particularities associated with the legal system in China, which could limit the legal protection available to us or to existing or potential investors.**

We conduct our business through our operating subsidiaries in China, which are governed by PRC law. China is a civil law jurisdiction based on written codes and statutes. Unlike common law jurisdictions, prior court decisions may be cited as persuasive authority but do not have legally binding force. The PRC government has promulgated laws and regulations in relation to economic matters in general, such as foreign investment, corporate organization and governance, commerce, taxation and trade, with a view to establishing a comprehensive legal system conducive to investment activities. However, the implementation, interpretation and enforcement of these laws and regulations may cause greater uncertainty compared to those in common law jurisdictions due to a relatively short legislative history, limited volume of court cases and their non-binding nature. Furthermore, many laws, regulations and legal requirements have only recently been adopted by the central or local government authorities, and their implementation, interpretation and enforcement may involve uncertainty due to the lack of established practice available for guidance. The PRC administrative authorities and courts also have significant discretion in interpreting and enforcing statutory and contractual terms. It thus may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection available than in more developed legal systems. These uncertainties may also impede our ability to enforce the contracts we have entered into with our business partners, customers and suppliers. Depending on the government authority or how an application or a case is presented to such authority or other factors, we may receive less favorable application of law. In addition, any litigation or legal proceeding in China may be protracted and result in substantial legal costs and diversion of resources and management attention. We cannot predict the effect of future legal developments in China, including promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, the preemption over local rules and regulations by national law, the overturn or modification of the lower-level authority's decisions at the higher level, or the changes in judiciary and administrative practices. As a result, there is substantial uncertainty as to the legal protection available to us or to our investors.

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**Future changes in laws, regulations or enforcement policies and practices in China could adversely affect our operations.**

Laws, regulations or enforcement policies in China, including those regulating healthcare and the pharmaceutical industry, are evolving and subject to frequent changes. Currently, the PRC pharmaceutical industry is highly regulated and many aspects of our business depend on the receipt of the relevant government authorities' approvals, licenses, certificates and permits. Further, regulatory agencies in China may periodically, and sometimes abruptly, change their enforcement practices. 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 protracted and may result in substantial cost 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, on November 11, 2015, the NMPA issued the Announcement on Certain Policies in relation to the Review and Approval of Drug Applications (《關於藥品註冊審評審批若干政策的公告》), which set out ten key points to be applied in the process of reviewing and approving drug applications and clinical trials, with an emphasis on the accuracy of clinical trials data and effectiveness of the drug. Our future drug applications are now subject to more strict approving standard.

**There are significant uncertainties under the EIT Law with respect to our PRC enterprise income tax liabilities, and with respect to possible PRC withholding tax imposed upon our shareholders.**

There are significant uncertainties under the EIT Law, which came into effect on January 1, 2008, and amended as of February 24, 2017 and December 29, 2018, and its implementation rules.

Under the EIT Law and its implementation rules, enterprises organized under the laws of jurisdictions outside the PRC with their “de facto management bodies” located within the PRC may be considered as “PRC resident enterprises” and subject to a uniform 25% PRC income tax on their worldwide income. The implementation rules to the EIT Law define the term “de facto management body” as “body that has material and overall management and control over the manufacturing and business operations, personnel and human resources, finances and treasury, properties and other assets of an enterprise.” The Notice on Identifying Chinese-Controlled Offshore Enterprises as Chinese Resident Enterprises in accordance with Criteria for Determining de facto management body (《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》), which was promulgated on April 22, 2009 and was amended on January 29, 2014 by the Determination of Resident Enterprises Based on the Standards of de facto management body (《關於依據實際管理機構標準實施居民企業認定有關問題的公告》), and has been partially abolished on December 29, 2017 by the SAT pursuant to Decision of the State Administration of Taxation on Issuing the Catalogues of Tax Departmental Rules and Tax Regulatory Documents Which Are Invalidated (《國家稅務總局關於公佈失效廢止的稅務部門規章和稅收規範性文件目錄的決定》) and the Administrative Measures on the

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Corporate 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)》) issued on July 27, 2011, and amended on April 17, 2015, June 15, 2018, and partially abolished on June 28, 2016, respectively, set out certain criteria for what constitutes a “de facto management body” in respect of enterprises that are established offshore by the PRC enterprises, which could be applied in determining the tax resident status of the non-PRC enterprises. Currently we are not Chinese-controlled offshore incorporated enterprises, however, the aforementioned factors may be considered by the SAT when determining our tax resident status for PRC EIT purpose.

As substantially all of the operational management of our Company is currently based in the PRC, we and our offshore subsidiaries may be deemed to be “PRC resident enterprises” for the purpose of the EIT Law. If we or our offshore subsidiaries are deemed PRC resident enterprises, we could be subject to EIT tax at 25% on our global income, except that the dividends we receive from our PRC subsidiaries may be exempt from the EIT to the extent such dividend income constitutes “the qualified dividends received by a PRC resident enterprise from its directly invested entity that is also a PRC resident enterprise.” It is, however, unclear what type of enterprise would be deemed a “PRC resident enterprise” for such purposes. If we or our offshore subsidiaries are deemed a PRC resident enterprise and earn significant income other than exempted dividends from our PRC subsidiaries, the EIT on our global income could significantly increase our tax burden and adversely affect our cash flows and profitability.

Further, pursuant to the EIT Law and its implementation rules, PRC income tax at the rate of 10% is generally applicable to PRC source dividends paid by “PRC resident enterprises” to investors that are “non-PRC residents” unless otherwise reduced or exempted by relevant tax treaties or similar arrangement. Similarly, any gain realized on the transfer of the shares of “PRC resident enterprises” by such investors is subject to the PRC income tax, usually at the rate of 10% unless otherwise reduced or exempted by relevant tax treaties or similar arrangements, if such gain is regarded as income derived from sources within the PRC. Accordingly, if we are deemed a PRC resident enterprise under the EIT Law, our shareholders that are “non-PRC resident enterprises” could be subject to the withholding income tax upon the dividends payable by us or upon any gains realized from the transfer of our Shares at the rate of 10% unless otherwise reduced or exempted. Meanwhile pursuant to the Individual Income Tax law and its implementation rules, dividends or gains received by non-PRC resident individuals may be subject to the PRC individual income tax at a rate of 20%.

It is unclear whether, if we and our offshore subsidiaries are deemed a PRC resident enterprise, our shareholders would be able to claim the benefit of income tax treaties entered into between China and other countries or regions. If dividends payable to our shareholders that are “non-PRC residents,” or gains from the transfer of our Shares are subject to the PRC income tax, the value of such shareholders’ investment in our Shares may be materially and adversely affected.

**The heightened scrutiny over acquisitions from the PRC tax authorities may have an adverse impact on our business, acquisition strategies or the value of your investment in us.**

On February 3, 2015, the PRC State Administration of Taxation issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets

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by Non-Resident Enterprises (《國家稅務總局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》) (the “**Circular 7**”), which provided comprehensive guidelines relating to, and also heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise (the “**PRC Taxable Assets**”).

For example, Circular 7 specifies that the PRC tax authorities are entitled to reclassify the nature of an indirect transfer of the PRC Taxable Assets, when a non-resident enterprise transfers the PRC Taxable Assets indirectly by disposing of equity interests in an overseas holding company directly or indirectly holding such PRC Taxable Assets, by disregarding the existence of such overseas holding company and considering the transaction to be a direct transfer of the PRC Taxable Assets, if such transfer is deemed to have been conducted for the purposes of avoiding the PRC EIT and without any other reasonable commercial purpose. When determining whether there is a “reasonable commercial purpose” of such transfer, factors to be taken into consideration include (i) whether the main value of the equity interest of the relevant offshore enterprise derives from the PRC Taxable Assets; (ii) whether the assets of the relevant non-resident enterprises mainly consists of direct or indirect investment in the PRC or if its income mainly derives from the PRC; (iii) whether the non-resident enterprises and its subsidiaries directly or indirectly holding the PRC Taxable Assets have real commercial substance which is evidenced by their actual function and risk exposure; (iv) the duration of existence of the shareholders, business model and organizational structure of the relevant offshore enterprises; (v) the substitutability of the transaction by direct transfer of the PRC Taxable Assets; and (vi) the tax situation of an indirect transfer and applicable tax treaties or similar arrangements.

We have conducted and may conduct acquisitions involving changes in our corporate structure, and historically our Shares were transferred by certain then shareholders to the current shareholders. Although Circular 7 contains certain exemptions (including, (i) where a non-resident enterprise derives income from the indirect transfer of the PRC Taxable Assets by acquiring and selling shares of a listed overseas holding company which holds such PRC Taxable Assets on a public market; and (ii) where there is an indirect transfer of the PRC Taxable Assets, but if the non-resident enterprise had directly held and disposed of such PRC Taxable Assets, the income from the transfer would have been exempted from enterprise income tax in the PRC under an applicable tax treaty or arrangement), it remains unclear whether any exemptions under Circular 7 will be applicable to the transfer of our Shares or to any future acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will, at their discretion, reclassify such transaction by applying Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving the PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities.

**If the beneficial owners of our Shares who are PRC residents fail to comply with certain PRC regulations relating to investments in offshore companies by PRC residents, our ability to distribute profits and our overseas and cross-border investment activities could be restricted, and we could be subject to liabilities under PRC laws.**

The SAFE has promulgated several regulations requiring the PRC residents to register with the PRC government authorities before engaging in direct or indirect offshore investment activities,



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including the Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents in China via Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “**Circular 37**”), issued and effective on July 4, 2014, 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》), issued on July 13, 2009 and effective on August 1, 2009 and the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) (the “**Circular 13**”), issued on February 13, 2015 and effective on June 1, 2015. Circular 37 requires PRC resident individuals and entities 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 resident individuals or entities, referred to in Circular 37 as a “special purpose vehicle” (the “**SPV**”). Circular 37 further requires timely amendment to the registration with the SAFE in the event of any fundamental or significant changes with respect to the SPV. Circular 13 cancels the administrative approval of confirmation of foreign exchange registration under overseas direct investment by the SAFE. Instead, qualified banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

If our Shareholders or beneficial owners who are PRC resident individuals or entities do not complete their registration, approval or filing with the local SAFE branches, NDRC or MOFCOM or its branches relating to the overseas investment activities, 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. Moreover, failure to comply with the various SAFE registration requirements described above could result in liabilities for our PRC subsidiaries under the 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 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. Furthermore, the persons-in-charge and other persons at our PRC subsidiaries who are held directly liable for the violations may be subject to criminal sanctions. In addition, our shareholders who are PRC entities may be ordered to suspend or stop the investment and to complete the registration, approval or filing within a specified time, and may be warned or prosecuted for relevant liabilities.

We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant rules. However, we may not always be fully aware or informed of the identities of our beneficiaries who are PRC resident individuals or entities, and may not always be able to compel them to comply with Circular 37 or other regulations relating to overseas investment activities issued by SAFE, NDRC and MOFCOM. As a result, there can be no assurance that all of our current or future Shareholders or beneficial owners who are PRC resident

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individuals or entities will at all times comply with, or in the future make or obtain any applicable registrations, filings or approvals required by, Circular 37 or other regulations relating to overseas investment activities issued by SAFE, NDRC and MOFCOM. Failure by any such Shareholders or beneficial owners to comply with Circular 37 or other regulations relating to overseas investment activities issued by SAFE, NDRC and MOFCOM could subject us to fines or legal sanctions, restrict our overseas or cross-border investment activities, limit our subsidiaries' ability to make distributions, pay dividends or other payments to us or affect our ownership structure, which could adversely affect our business and prospects.

**Fluctuations in exchange rates may result in foreign currency exchange losses and may have a material adverse effect on your investment.**

The change in the value of the Renminbi against the Hong Kong dollar and other currencies may fluctuate and be affected by, among other things, changes in China's political and economic conditions. For instance, in the PRC from 1995 until July 2005, the conversion of the Renminbi into foreign currencies, including the Hong Kong dollar and U.S. dollar, has been based on fixed rates set by the People's Bank of China (the "PBOC"). The PRC government, however, has, with effect from July 21, 2005, reformed the exchange rate regime by moving into a managed floating exchange regime based on market supply and demand with reference to a basket of currencies. On July 21, 2005, this revaluation resulted in the Renminbi appreciating against the U.S. dollar and the Hong Kong dollar by approximately 2% on that date. On September 23, 2005, the PRC government widened the daily trading band for the Renminbi against non-U.S. dollar currencies from 1.5% to 3.0% to improve the flexibility of the new foreign exchange system. As a consequence, Renminbi has fluctuated sharply since July 2008 against other freely traded currencies, in tandem with the U.S. dollar. On June 19, 2010, the PBOC announced that it intended to further reform the Renminbi exchange rate regime by enhancing the flexibility of the Renminbi exchange rate. On March 17, 2014, the PBOC enlarged the previous floating band of the trading prices of the Renminbi against the U.S. dollar in the inter-bank spot foreign exchange market from 1% to 2% in order to further improve the managed floating Renminbi exchange rate regime based on market supply and demand with reference to a basket of currencies. However, it remains unclear how this flexibility might be implemented. The Renminbi was added to its group of global reserve currencies by The International Monetary Fund on November 30, 2015, which makes Renminbi to some extent more susceptible to market forces as the PRC government loosens some of its currency controls.

We may receive dividends and other fees paid by PRC subsidiaries. Any significant change in the exchange rates of the Hong Kong dollar against Renminbi may materially and adversely affect our cash flows, earnings and financial position, and the value of, and any dividends payable on, our Shares in Hong Kong dollars. For example, an appreciation of Renminbi against the Hong Kong dollar would make any new Renminbi-denominated investments or expenditures more costly to us, to the extent that we need to convert Hong Kong dollars into Renminbi for such purposes. An appreciation of Renminbi against the Hong Kong dollar would also result in foreign currency translation losses for financial reporting purposes when we translate our Hong Kong dollar denominated financial assets into Renminbi, including proceeds from the Global Offering, as Renminbi is the functional currency of our subsidiaries inside China. Conversely, if we decide to convert our Renminbi into Hong Kong dollars for the purpose of making payments for dividends on

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our Shares or for other business purposes, appreciation of the Hong Kong dollar against Renminbi would have a negative effect on the Hong Kong dollar amount available to us.

**Government control of currency conversion of and regulations on loans to, and direct investment in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional contributions to our PRC subsidiaries, which could restrict our ability to utilize the proceeds from the Global Offering effectively and affect our ability to fund and expand our business.**

The PRC government imposes controls on the convertibility of foreign currencies into Renminbi. Under China's existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, the PRC governmental authorities. In particular, if one of our PRC subsidiaries receives foreign-currency loans from us or other foreign lenders, these loans must be registered with the SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed and registered with certain PRC government authorities, including the MOFCOM or its local counterparts and the SAMR through its 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 the SAFE.

In August 2008, the SAFE promulgated the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Exchange Capital Funds of Foreign Invested Enterprises (《國家外匯管理局綜合司關於完善外商投資企業外匯資本金支付結匯管理有關業務操作問題的通知》), or SAFE Circular 142, providing that the Renminbi capital converted from foreign exchange capital funds of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within the PRC.

On March 30, 2015, the SAFE released the Notice on the Reform of the Management Method for the Settlement of Foreign Exchange Capital Funds of Foreign-invested Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or SAFE Circular 19, which came into force and superseded SAFE Circular 142 from June 1, 2015 and was partially abolished on December 30, 2019. On June 9, 2016, the SAFE further promulgated the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (《關於改革和規範資本項目結匯管理政策的通知》), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital funds of foreign-invested enterprises, and some foreign exchange restrictions under SAFE Circular 142 are expected to be lifted. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange under capital accounts by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 and SAFE Circular 16 also reiterate that the settlement of foreign exchange under capital accounts shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. Under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign exchange capital funds of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment

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except for principal-guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using Renminbi converted from its registered capital funds to provide loans to a its non-affiliated company. Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

On October 23, 2019, the SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), or SAFE Circular 28, according to which a non-investment foreign-invested enterprise is permitted to make domestic equity investments with its capital funds provided that such investments do not violate the Negative List and the target investments are genuine and in compliance with laws. On April 10, 2020, the SAFE promulgated the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》), or SAFE Circular 8, under which eligible enterprises are allowed to make domestic payments by using their capital funds, foreign loans and the income under capital accounts of overseas listing, without providing the evidentiary materials concerning authenticity of each expenditure in advance, provided that their capital use shall be authentic, and conform to the prevailing administrative regulations on the use of income under capital accounts. Considering that SAFE Circular 28 and SAFE Circular 8 are often principle-oriented and subject to the detailed interpretations by the enforcement bodies to further apply and enforce such laws and regulations in practice, it is unclear how they will be implemented, and there can be high uncertainties with respect to its interpretation and implementation by government authorities and banks.

### **Inflation in the PRC could negatively affect our profitability and business prospects.**

Economic growth in the PRC has in the past been accompanied by periods of high inflation, and the PRC government has implemented various policies from time to time to control inflation. For example, the PRC government introduced measures in certain sectors to avoid overheating of the economy, including tighter bank lending policies and increases in bank interest rates. The effects of the stimulus measures implemented by the PRC government since the global economic crisis that unfolded in 2008 may have contributed to the occurrence of, and continuing increase, in inflation in China. If such inflation is allowed to proceed without mitigating measures by the PRC government, our cost of sales would likely increase, and our profitability would be materially reduced, as there is no assurance that we would be able to pass any cost increases onto our customers. If the PRC government implements new measures to control inflation, these measures may also slow economic activity and reduce demand for our products and services and severely hamper our growth.

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**We rely on dividends paid by our subsidiaries for our cash needs, and limitations under the PRC laws on the ability of our PRC subsidiaries to distribute dividends to us could adversely affect our ability to utilize such funds.**

As a holding company, we conduct substantially all of our business through our consolidated subsidiaries incorporated in China. We rely on dividends paid by these PRC subsidiaries for our cash needs, including the funds necessary to pay any dividends and other cash distributions to our Shareholders, to service any foreign currency debt we may incur and to make any offshore acquisitions. The payment of dividends by entities established in China is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. Each of our PRC subsidiaries is required to set aside (i) at least 10% of its after-tax profit based on PRC accounting standards each year to its general reserves or statutory capital reserve funds until the aggregate amount of such reserves reaches 50% of its respective registered capital; and (ii) discretionary reserve funds as approved by its shareholders meeting. As a result, our PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to us in the form of dividends, loans or advances. We anticipate that in the foreseeable future our PRC subsidiaries will need to continue to set aside 10% of their respective after-tax profits to their statutory reserves. In addition, certain loan agreements signed by our PRC subsidiaries in the future may contain covenants that restrict their ability to pay out dividends. These limitations on the ability of our PRC subsidiaries to transfer funds to us limit our ability to receive and utilize such funds.

**If we fail to comply with PRC regulations regarding the registration requirements for employee stock incentive plans, we and the PRC plan participants could be subject to fines and other legal or administrative sanctions.**

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Company (《國家外匯管理局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》) (the “**Stock Option Rules**”), which replaced the earlier rules promulgated by the SAFE in March 2007. Under the Stock Option Rules, the PRC citizens and non-PRC citizens residing in China for a continuous period of no less than one year (except for foreign diplomatic personals in China and the representatives of international organizations in China) who participate in stock incentive plans in an overseas publicly listed company are required, through a PRC agent entrusted by the domestic company which these participants serve for and is affiliated to the overseas publicly listed company, to register with the SAFE and complete certain other procedures. 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 agent is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan, the PRC agent or the overseas entrusted institution or other material changes.

We and our PRC resident employees who have been granted stock options will be subject to the Stock Option Rules upon completion of this Global Offering. Failure of the PRC plan participants to complete their SAFE registrations may subject these PRC residents to fines and legal sanctions and

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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.

**There may be difficulties in effecting services of process and seeking recognition and enforcement of foreign judgments against us in China based on foreign laws.**

Part of our assets are located in China, and most of our senior management members and directors reside in China. However, China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by the courts of the U.S. or many other jurisdictions. As a result, it may be difficult or impossible for investors to effect service of process or enforce certain court judgments against our PRC subsidiaries, our assets, senior management members or directors in China.

On July 14, 2006, the government of the Hong Kong Special Administrative Region and the Supreme People's Court of the PRC 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》) (the “**2006 Arrangement**”), pursuant to which a party with a final court judgment rendered by a Hong Kong 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 the judgment in the PRC. Similarly, a party with a final judgment rendered by a PRC 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 the judgment in Hong Kong. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the 2006 Arrangement in which a Hong Kong court or a PRC court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in dispute have not agreed to enter into such a choice of court agreement in writing. Although the 2006 Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the 2006 Arrangement may still be uncertain.

On January 18, 2019, the Supreme People's Court of the PRC and the government of the Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgements 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》) (the “**2019 Arrangement**”). Although the 2019 Arrangement has been signed, it remains unclear when it will come into effect. When the 2019 Arrangement becomes effective, it will supersede the 2006 Arrangement and any party concerned may apply to the relevant PRC court or Hong Kong High Court for recognition and enforcement of the effective judgements in civil and commercial cases under the 2019 Arrangement but will be subject to the conditions set forth in the 2019 Arrangement. Therefore, the outcome and effectiveness of any action brought under the 2019 Arrangement is still uncertain. We cannot assure you that an effective judgement that complies with the 2019 Arrangement can be recognized and enforced in a PRC court.

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### RISKS RELATING TO THE GLOBAL OFFERING AND OUR SHARES

**No public market currently exists for our Shares. The market price for our Shares may be volatile and an active trading market for our Shares may not develop.**

No public market currently exists for our Shares. The initial Offer Price for our Shares to the public will be the result of negotiations between our Company and the Joint Representatives (for themselves and on behalf of the Underwriters), and the Offer Price may differ significantly from the market price of the Shares following the Global Offering. We have applied to the Stock Exchange for the listing of, and permission to deal in, the Shares. A listing on the Stock Exchange, however, does not guarantee that an active and liquid trading market for the Shares will develop, or if it does develop, that it will be sustained following the Global Offering, or that the market price of the Shares will not decline following the Global Offering.

In addition, the trading price and trading volume of the Shares may be subject to significant volatility in responses to factors including:

- variations in our operating results;
- changes in financial estimates by securities analysts;
- announcements made by us or our competitors;
- regulatory developments in China affecting us, our customers or our competitors;
- investors' perception of us and of the investment environment in Asia, including Hong Kong and Mainland China;
- developments in China's healthcare market;
- changes in pricing made by us or our competitors;
- acquisitions by us or our competitors;
- the depth and liquidity of the market for our Shares;
- additions to or departures of, our executive officers and other members of our senior management;
- release or expiry of lock-up or other transfer restrictions on our Shares;
- sales or anticipated sales of additional Shares; and
- the general economy and other factors.

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 price not directly related to our performance.

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

The Offer Price of the Offer Shares is higher than the net tangible asset value per Share immediately prior to the Global Offering. Therefore, purchasers of the Offer Shares in the Global

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Offering will experience an immediate dilution in pro forma consolidated net tangible asset value to HK\$2.21 per Share, based on the mid-point of the Offer Price range of HK\$18.00. There can be no assurances that if we were to immediately liquidate after the Global Offering, any assets will be distributed to Shareholders after the creditors' claims. In order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the Offer Shares 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 the net tangible asset value per Share at that time.

**Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.**

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make such rights available to persons in the United States unless we register both the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective and we may not be able to establish a necessary exemption from registration under the U.S. Securities Act. Accordingly, you may be unable to participate in our rights offerings in the future and may experience dilution in your holdings.

**Future sales or perceived sales of our Shares in the public market by major Shareholders following the Global Offering could materially and adversely affect the price of our Shares.**

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

**Our single largest Shareholder has significant influence over our Company and its interests may not be aligned with the interests of our other Shareholders.**

Immediately following the Global Offering, our single largest Shareholder will hold in aggregate approximately 28.78% of our Shares, assuming the Over-allotment Option is not exercised. Our single largest Shareholder will, through its voting power at the Shareholders' meetings and their delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our single largest Shareholder may not act in the best interests of our minority Shareholders. In addition, without the consent of our single largest Shareholder, we



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could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our Shares.

**There will be a gap of several days between pricing and trading of our Shares, and the price of our Shares when trading begins could be lower than the Offer Price.**

The initial price to the public of our Shares sold in the Global Offering is expected to be determined on the Price Determination Date. However, the Shares will not commence trading on the Stock Exchange until they are delivered, which is expected to be not more than five Business Days after the Price Determination Date. As a result, investors may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the price of the Shares when trading begins could be lower than the Offer Price as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time trading begins.

**If securities or industry analysts do not publish research reports about our business, or if they adversely change their recommendations regarding our Shares, the market price and trading volume of our Shares may decline.**

The trading market for our Shares relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If research analysts do not maintain adequate research coverage or if one or more of the analysts who covers us downgrades our Shares or publishes inaccurate or unfavorable research about our business, the market price for our Shares would likely decline. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our Shares to decline significantly.

**There can be no assurances that we will declare and distribute any dividend in the future.**

As a holding company, our ability to declare future dividends will depend on the availability of dividends, if any, received from our PRC operating subsidiaries. Under PRC law and the constitutional documents of our PRC operating subsidiaries, dividends may be paid only out of distributable profits, which refers to after tax profits as determined under PRC GAAP less any recovery of accumulated losses and required allocations to statutory capital reserve funds. Any distributable profits that are not distributed in a given year are retained and become available for distribution in subsequent years. The calculation of our distributable profits under PRC GAAP differs in many aspects from the calculation under HKFRS. As a result, our PRC operating subsidiaries may not be able to pay a dividend in a given year if they do not have distributable profits as determined under PRC GAAP, even if they have profits as determined under HKFRS. Accordingly, since our Company derives substantially all of our earnings and cash flows from dividends paid to us by our PRC operating subsidiaries in China, we may not have sufficient distributable profits to pay dividends to our Shareholders.

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See “Financial Information — Dividend Policy” for further details of our dividend policy. There can be no assurances that future dividends will be declared or paid. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors depending on, among other considerations, our operations, earnings, financial condition, cash requirements and availability, our constitutional documents and applicable law.

**We are a Cayman Islands company, and you may have different protection of your shareholder rights than you would have under Hong Kong law.**

Our corporate affairs are governed by our Memorandum, Articles, the Companies Act and the common law of the Cayman Islands. The rights of Shareholders to take action against our Directors, actions by minority shareholders and the fiduciary responsibilities of our Directors 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 rights of our Shareholders and the fiduciary responsibilities of our Directors under the Cayman Islands law are not as clearly established as they would be under statutes or judicial precedents in Hong Kong and other jurisdictions. See “Summary of the Constitution of the Company and Cayman Company Law” in Appendix IV to this prospectus. As a result, our Shareholders may encounter different issues in protecting their interests through actions against our management, Directors or major Shareholders compared to shareholders of a corporation incorporated in Hong Kong or other jurisdictions.

**We cannot guarantee the accuracy of official government facts, forecasts and other statistics with respect to China, the Chinese economy and China’s pharmaceutical and healthcare industries and data of clinical trials and studies from academic journals contained in this prospectus.**

Official government facts, forecasts and other statistics in this prospectus relating to China, the Chinese economy and China’s pharmaceutical and healthcare industries have been derived from official government publications, and certain data of clinical trials and studies have been derived from authoritative academic journals. We believe that the sources of such information are appropriate sources, and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information has not been independently verified by us, the Joint Sponsors or any other party involved in the Global Offering, and no representation is given as to its accuracy. In all cases, investors should give consideration as to how much weight or importance they should attach to or place on such official government facts, forecasts or statistics or data of clinical trials and studies from academic journals.

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## RISK FACTORS

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**You should read the entire prospectus carefully and we strongly caution you not to place any reliance on any information contained in press articles and/or other media regarding us, our business, our industries and the Global Offering.**

There has been, prior to the publication of this prospectus, and there may be subsequent to the date of this prospectus but prior to the completion of the Global Offering, press and/or media regarding us, our business, our industry and the Global Offering. You should rely solely upon the information contained in this prospectus in making your investment decisions regarding our Shares. None of us, the Joint Sponsors, or any other person involved in the Global Offering have authorized the disclosure of any such information in the press or media and none of these parties accept any responsibility for the accuracy or completeness of the information contained in such press articles and/or other media or the fairness or appropriateness of any forecasts, views or opinions expressed by the press and/or other media regarding our Shares, the Global Offering, our business, our industries or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information, forecasts, views or opinions expressed or any such publications. To the extent that such statements, forecasts, views or opinions are inconsistent or conflict with the information contained in this prospectus, we disclaim them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this prospectus only and should not rely on any other information.