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## RISK FACTORS

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*An investment in the Offer Shares involves various risks. You should carefully consider all the information in this prospectus and in particular the risks and uncertainties described below before making an investment in the Offer Shares.*

*The occurrence of any of the following events could materially and adversely affect our business performance, financial condition, results of operations or prospects. If any of these events occur, the trading price of the Offer Shares could decline and you may lose all or part of your investment. You should seek professional advice from your relevant advisers regarding your prospective investment in the context of your particular circumstances.*

### **RISKS RELATING TO OUR BUSINESS AND INDUSTRY**

***If our products are excluded or removed from national, provincial or other government-sponsored medical insurance programs, or are included in any national or provincial negative catalogs, our sales, profitability and business prospects could be materially and adversely affected.***

Under medical insurance programs in the PRC, patients are entitled to full or partial reimbursement of costs for pharmaceutical products listed in the NRDL or relevant provincial medical insurance catalogs, or included in provincial insurance schemes regarding special medications for the treatment of major diseases. According to the National Healthcare Security Administration and Frost & Sullivan, approximately 1,354.4 million people in China were enrolled in Employee Basic Medical Insurance Scheme and Urban and Rural Residents Basic Medical Insurance Scheme in 2019, representing 96.7% of the entire population in China. Consequently, the inclusion or exclusion of a pharmaceutical product in or from any of such medical insurance catalogs, or any limitation imposed on the coverage of a pharmaceutical product, will significantly affect the demand for such product in the PRC. As of the Latest Practicable Date, eight of our major products were included in the NRDL; our revenue from sales of these eight major products accounted for 50.0%, 53.6%, 60.9% and 66.7% of our total revenue, respectively, for the years ended December 31, 2017, 2018 and 2019 and the six months ended June 30, 2020.

The selection of pharmaceutical products for listing in medical insurance catalogs is based on a variety of factors, including clinical needs, frequency of use, effectiveness, safety and price, many of which are outside 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 already listed in any medical insurance catalog. There can be no assurance that any of our products currently listed in these medical insurance catalogs will remain listed, or that changes in the scope of reimbursement will not negatively affect our products. If any of our products or their indications are removed from any medical insurance catalog, or if the scope of reimbursement is reduced, demand for our products may decrease and our revenue and profitability could be adversely affected. For example, edaravone

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was excluded from the latest version of NRDL, which was published in August 2019 and came into force in January 2020. The sales volume of our Bicun decreased as a result of such exclusion, and there is no assurance that it may not experience decrease in sales in the future. Furthermore, if we are unable to get new products listed in these medical insurance catalogs, our business prospects could be adversely affected.

In addition, NHC and National Administration of Traditional Chinese Medicine (國家中醫藥管理局) jointly issued the “First Batch of National Key Drug List for Monitoring and Prescription Control (Chemical and Biological Products)” (《第一批國家重點監控合理用藥藥品目錄(化藥和生物製品)》) (the “**Control List**”) in June 2019, which requires medical institutions to strictly monitor and control the clinical use of pharmaceuticals included therein, therefore significantly decreasing physicians’ capability as well as willingness to prescribe the relevant pharmaceuticals. The sales volume of our Bicun decreased in 2019 as a result of the issuance of the Control List. There can be no assurance that similar catalogs will be issued at national or provincial level, nor can we predict future pharmaceutical coverage of such catalogs. If any of our products are included in such negative catalogs, demand for our products may decrease and our revenue and profitability could be adversely affected.

*The prices of certain of our products are subject to pricing regulation, competition and other factors and therefore may decrease, which could materially and adversely affect our profitability.*

It is typical in China that the prices of pharmaceutical products will decline over the life of the product as a result of, among other things, the centralized tender process, pricing regulation by the PRC government, or increased competition from substitute products, including due to price adjustments by pharmaceutical companies (producers of the originator brands), whether or not voluntarily or as a result of government regulations or policies. The importation of competing products from countries where government price controls or other market dynamics result in lower prices may also exert downward pressure on the prices of our products.

Prior to June 1, 2015, price controls in the PRC pharmaceutical industry were mainly in the form of maximum retail prices. In May 2015, pursuant to a notice issued by seven PRC State agencies including the NDRC and the NMPA, government price controls on pharmaceutical products were lifted as of June 1, 2015. As a result, prices of pharmaceutical products are currently mainly determined by market competition through the centralized tender processes at the provincial level, without 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 our products upon commercialization to the previous government-controlled price levels.

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The prices of our products have been susceptible to pricing pressure coming from manufacturers of competing products. In addition, the lifting of price ceilings, which provided more incentives for manufacturers to develop innovative products, could also adversely affect the wholesale prices at which we can sell the relevant products to our distributors. Under the terms of our distribution agreements, we and the relevant distributor may adjust the supply price of our products in the event of a price change as a result of regulatory or policy changes or centralized tender processes. However, in the event that any retail price changes after our products are delivered to our distributors but before they are sold to medical institutions, we may bear the upside potential as well as downside risk from any such retail price change for the relevant products. The financial impact of such price adjustments is insignificant to our total revenue during the Track Record Period.

In addition, PRC government authorities may reform the schemes of pricing control and statutory tender processes for pharmaceutical products or revise other policies affecting prices of pharmaceutical products over time. For example, under the Guiding Opinions of the General Office of the State Council on Improving Centralized Purchasing of Drugs for Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) issued in February 2015, hospitals are encouraged to directly settle the prices of pharmaceutical products with manufacturers. This policy is intended to reduce the hospital retail prices of pharmaceutical products by eliminating the intermediaries between hospitals and manufacturers. Consolidated procurement and direct settlement between hospitals and manufacturers may increase the bargaining power of hospitals and increase the pricing pressure on our existing and future products.

In November 2018, the Joint Procurement Office led by the State Administration for Medical Insurance published the “Papers on Centralized Drug Procurement in “4+7” Cities” (《4+7城市藥品集中採購文件》) (the “**Papers**”), which launched the national pilot scheme for centralized volume-based drug procurement. The Papers listed 31 drugs for this pilot scheme together with an intended volume commitment for each drug. The manufacturers and importers of the drugs 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” (the “**Notice**”) (《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》). The Notice provides additional detailed measures in the implementation of the national pilot scheme for centralized volume-based drug procurement in the “4+7” cities. Among the 31 drugs listed in the Papers for the pilot scheme, 25 drugs were successfully procured. In September 2019, the Joint Procurement Office published the “Papers on Centralized Drug Procurement in Alliance Areas” (《聯盟地區藥品集中採購文件》), which further expanded the scope of centralized volume-based drug procurement of such 25 drugs to 25 provinces and autonomous regions (except for the “4+7” cities listed in the Papers). In December 2019, the Joint Procurement Office published the “Papers on Centralized Drug Procurement Nationwide” (《全國藥品集中採購文件》), listing 33 drugs for centralized

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procurement together with an intended volume commitment for each drug. Please see “Regulatory Overview – Major Regulatory Reforms in the Pharmaceutical Industry – Tender Process – The Centralized Volume-based Drug Procurement in “4+7 Cities” and Wider Areas” for more details.

As of the Latest Practicable Date, we only won the bids to supply our Biqi-branded diosmectite powder to public medical institutions in “4+7” cities and to supply our tofacitinib citrate tablets to public medical institutions nationwide at a discounted price. There are uncertainties with respect to future drug coverage of centralized drug procurement schemes. As a result, there can be no assurance that we may have additional drugs added to such schemes in the future, which may result in increased pricing pressure on us. If our competitors win the bid in such schemes while we fail to do so for our products with the same generic names, demands for our products may decrease and our revenue, profitability and market share could be adversely affected. Moreover, even if we win the bid for our products, there may be discrepancies between the estimated procurement volumes set out in the tender documents and the actual procurement volumes. Consequently, there are uncertainties with respect to the impact of the implementation of centralized drug procurement schemes on the sales volume as well as the revenue of the winning products.

In addition, innovative pharmaceuticals included in any national medical insurance negotiation list generally need to undergo pricing negotiation process with the PRC government. Endostar (recombinant human endostatin injection) has entered into the NRDL through pricing negotiation, which resulted in a decrease of its retail price across the country.

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

If the prices of our products decline due to government pricing regulation, emergence of substitute products or other market factors, we may not be able to mitigate the adverse effects of such price reduction without incurring substantial expenses to improve our products, and our margins and profitability could be materially and adversely affected.

***If we are unable to succeed in tender processes to sell our products to PRC public hospitals and other medical institutions, we may lose market share and our revenue and profitability could be materially and adversely affected.***

The majority of our products we sell to our distributors are then sold to public hospitals and other medical institutions owned or controlled by government authorities in China. Each of these institutions must generally procure pharmaceuticals through a centralized pharmaceutical procurement platform organized by local government authorities, and source substantially all of their pharmaceuticals through a centralized tender process. We and our competitors submit bids in such tender process to supply pharmaceutical products to these institutions at specified prices. The relevant government authorities evaluate these bids based on a number of criteria, such as bidding price, product quality, clinical effectiveness and reputation and after-sales service of the manufacturers. If we succeed in the tender process, the

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relevant products will be sold to the public hospitals and other medical institutions at the bid prices through our distributors, which is the primary determinant of the prices at which we sell these products to our distributors.

We may fail to win bids in a tender process due to various factors, including reduced demand for the relevant product, uncompetitive bidding price, failure to meet certain quality requirements, insufficient service quality to meet tender requirements, perception that our product is less clinically effective than competing products or our service or other aspects of our operations are less competitive. If our products are not selected in the tender processes in one or more regions, we will be unable to sell these products to the public hospitals and other medical institutions in those regions, and our market share, revenue and profitability could be adversely affected.

The tender processes can also create pricing pressure among substitute products or products that are perceived to be substitute products. Drug prices face further downward pressure from the centralized tender process in several provinces which requires that bids for a product should not exceed the lowest winning bid nationwide or the average of the five to 10 winning bids for the same product in designated provinces. Our sales volumes and profitability depend on our ability to successfully differentiate our products and price our bids in a manner that enables us to succeed in the centralized tender processes without compromising our profitability. If we are unable to differentiate our products or are otherwise not successful in winning bids in the centralized tender processes at profitable levels, our market share, results of operations and profitability could be adversely affected.

Furthermore, there are uncertainties as to when a province will commence its centralized tender process, and when the new prices will come into effect pursuant to the completion of a centralized tender process. The uncertain timeline in relation to the centralized tender process could materially and adversely affect our business, results of operations and prospects.

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

The PRC pharmaceutical industry is subject to extensive government regulation and supervision as well as monitoring by various 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 reassessment processes, registration of new drugs, quality control, pricing of pharmaceutical products and environmental protection. There can be no assurance that the legal framework, licensing and certification requirements or enforcement trends in our industry will not change in a manner that may result in increased costs of compliance, or that we will be successful in responding to such changes. In addition, we are subject to the risk of adverse changes to favorable governmental policies from which we currently benefit, and the introduction of unfavorable governmental policies. The costs we incur to comply with these

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laws and regulations may materially increase our total costs and decrease our profit. Any violation of these laws, rules or regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our production facilities and obligations to take rectification measures.

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》) (NMPA Notice No. 117 (2015)), 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 “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》) (NMPA Notice No. 140 (2015)), according to which the NMPA planned to apply the most stringent standards to review and approve the current drug applications. In addition, on November 11, 2015, the NMPA issued “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》) (NMPA Notice No. 230 (2015)), which set out 10 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, drug effectiveness and consistency between the originator version and the generic version as demonstrated in consistency evaluations. The combination of these policies indicates that pharmaceutical companies need to conduct self-review 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 the NMPA requirements are met. The more 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 February 2016, the General Office of the State Council issued the “Opinion on Conducting the Quality and Efficacy Consistency Evaluation of Generic Drugs” (《國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見》) (the “**February 2016 Opinion**”), which requires pharmaceutical manufacturers to evaluate the quality and efficacy of certain of their generic drugs within the prescribed time limits. Failure to timely complete such evaluation could cause previous approvals for the sale of relevant generic drugs to be revoked and make them ineligible for re-registration for sale. In August 2017, the NMPA issued the “Announcement of the China Food and Drug Administration on Relevant Matters Concerning the Quality and Efficacy Consistency Evaluation 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》) (NMPA Notice No. 100 (2017)), which sets out procedures for the application, approval, inspection and test of the consistency evaluation as required under the February 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》) (NMPA Notice No. 102 (2018)) which removed the uniform timelines for the oral solid preparations of chemical generic drugs included in the National Essential Drug List (2012 Edition) to complete the consistency evaluation. On

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May 12, 2020, the NMPA promulgated the “Circular on Conducting the Quality and Efficacy Consistency Evaluation for Generic Chemical Pharmaceuticals in the Form of Injections” (《關於開展化學藥品注射劑仿製藥質量和療效一致性評價工作的公告》), which requires marketed generic chemical pharmaceuticals in the form of injections to conduct consistency evaluation if they were not approved under the principle of being consistent with the quality and efficacy of originator pharmaceuticals. Marketing authorization holders of such generic pharmaceuticals shall submit applications and conduct consistency evaluation in accordance with detailed technical requirements promulgated by the NMPA. However, there remains significant uncertainty relating to the substantive and procedural requirements of the evaluation process, the interpretation of the relevant written requirements and procedures as well as associated costs, including costs in relation to conducting consistency evaluations. If we fail to complete the evaluation for our generic drugs, we may not be able to re-register such drugs for sale, or participate in the centralized tender process. If we fail to complete the bioequivalence test study, we may fail to obtain generic drugs approval, as a result of which, we cannot start production and sale of the relevant drugs. All of these may materially and adversely affect our business, financial condition, results of operations and prospects. Please refer to “Regulatory Overview – Laws and Regulations Relating to Drugs – Laws and Regulations on Drug Registration – Registration of Generic Drugs” for more details.

Legal and regulatory changes may lead to significant changes in the PRC pharmaceutical industry and could result in increased costs and lowered profit margins for manufacturers, distributors and retailers of pharmaceutical products. Any legal and regulatory changes could also lead to a decrease in the amounts of products purchased by our customers and/or the price of our products. We cannot assure you that we will be able to sufficiently and promptly respond to regulatory changes in the future, and such failure may have a material adverse effect on our business, financial condition, results of operations and profitability.

***If we or our business partners fail to maintain the necessary licenses for the development, production, promotion, sales and distribution of our products, our ability to conduct our business could be materially impaired and our revenue and profitability could be adversely affected.***

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. Please see “Business – Licenses, Permits and Certificates.” Our business partners, such as suppliers, distributors, third-party promoters and CROs, on whom we may rely to develop, produce, market, sell and distribute our products, may be subject to similar requirements. We and our business partners may also be subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or our business partners will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and

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certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or our business partners fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired.

Any changes in the standards used by governmental authorities in considering whether to renew or reassess our or our business partners' licenses, permits and certifications, as well as enactment of any new regulations that may restrict the operation 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 change, or new regulations come into effect, requiring us or our business partners to obtain any additional permits, licenses or certifications that were previously not required to operate our business, there can be no assurance that we or our business partners will successfully obtain such permits, licenses or certifications.

***We are dependent on sales of a limited number of major products. If we are unable to maintain the sales volumes, pricing levels and profit margins of our major products, our revenues and profitability could be adversely affected.***

We are dependent on sales of 10 major pharmaceutical products. Revenue from the sales of these products accounted for 85.1%, 83.0%, 81.9% and 78.9% of our total revenue for the years ended December 31, 2017, 2018 and 2019 and the six months ended June 30, 2020, respectively. We expect that revenue from the sales of these major products will continue to contribute a substantial portion of our revenue in the near future. If we are unable to maintain the sales volumes, pricing levels and profit margins of these major products, our revenue and profitability could be adversely affected.

Many of the factors discussed in this section could adversely affect sales of our major products, including, but not limited to, their exclusion or removal from the NRDL, relevant provincial medical insurance catalogs or the National Essential Drug List; competition and lack of success in the centralized tender process necessary for sales to public hospitals and other medical institutions in the PRC; pricing pressure caused by government policies and competition; market acceptance among the medical community; interruptions in the supply of raw materials; increases in the cost of raw materials; disruptions in manufacturing or distribution; issues with product quality or side effects; and disputes over intellectual property rights. Moreover, despite our efforts, we may be unable to develop or acquire new products that would diversify our business and reduce our dependence on our major products in a timely or competitive manner, or at all.



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***Failure to achieve or maintain widespread market acceptance for our products may have an adverse impact on our operations, profitability and prospects.***

The commercial success of our products, including existing or future products, is highly dependent on their continued market acceptance among healthcare practitioners and patients. We believe that the market acceptance of our products depends on many factors, including:

- The perceived advantages of our products over competing products and the availability and success of competing products;
- the safety and efficacy of our products and the prevalence and severity of side effects, if any;
- the pricing and cost effectiveness of our products;
- the effectiveness of our sales and marketing efforts;
- publicity concerning our products or competing products; and
- our ability to respond to changes in needs and preferences of healthcare practitioners and patients.

In addition, market acceptance of a product is also affected by whether it is included in the NRDL or provincial medical insurance catalogs. Please see “– If our products are excluded or removed from national, provincial or other government-sponsored medical insurance programs, or are included in any national or provincial negative catalogs, our sales, profitability and business prospects could be materially and adversely affected.” During the Track Record Period, at our own discretion, we accepted partial return of one of our products which remained unsold due to a change of relevant government policies, the total amount of which was immaterial. 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 business and profitability may be materially and adversely affected.

***We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors, which could adversely affect our revenue and profitability.***

We operate in a highly competitive environment and we may not be able to compete effectively against current and future competitors. Our inability to compete effectively could result in decrease of sales, reduction of price and loss of market share, any of which could have a material adverse effect on our results of operations and profit margins.

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Our key competitors are large national and regional manufacturers of pharmaceutical products, including large State-owned pharmaceutical companies. We also compete with multinational pharmaceutical companies. Our products primarily compete with products that are indicated for similar conditions as our products on the basis of efficacy, safety, price, brand, general market acceptance and recognition. Our competitors may be able to more quickly or more successfully discover, develop, acquire or market effective substitutes for our products for a number of reasons, including:

- the patents for certain products in our product portfolio, as well as certain product candidates we intend to develop, do not cover the underlying APIs. Therefore, our competitors may formulate substitute products utilizing the same APIs. In addition, the patents for certain products in our product portfolio have expired or will expire in a short period of time. Following the expiration of the relevant patents, our existing or future competitors may be able to develop and introduce substitute products to our products which may be identical in formulation;
- we sourced APIs for certain of our products from third-party suppliers, some of whom are our competitors and are well-positioned to compete with us leveraging their strong control over the APIs essential for the production of our relevant products;
- a majority of our major products have been sold in the PRC market for more than 10 years, which makes these products susceptible to substitute products 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;
- our products typically target conditions that are in high demand for medical treatment in China, and, as a result, our competitors, some of whom may have greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than us, may elect to focus these 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 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.

Some of our products are generic pharmaceuticals, and they face strong competition from the originator drugs and other generic versions, which may be sold at lower prices and therefore put pricing pressure on our products. Certain of our products are first-to-market generic pharmaceutical products, and the protection or monitoring period, during which period the NMPA would not accept NDA for the same product or approve the production or import of the same product by other pharmaceutical companies, has lapsed. Therefore, other

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pharmaceutical companies may obtain the relevant production approvals to sell generic pharmaceutical products with similar formulation or production processes in China, which could subject us to additional competition and adversely affect our business and results of operations. If we fail to protect our products from competition and remain competitive, our revenue and profitability may be materially and adversely affected.

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. If pharmaceutical products manufactured overseas are perceived more favorably than products manufactured domestically in the PRC, it could erode our market share and have a material and adverse impact on our results of operations and prospects.

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

***We may fail to sufficiently and promptly respond to rapid scientific and technological changes, clinical demand and market changes in the pharmaceutical industry.***

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 research and 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 adverse effect on our business, financial condition, results of operations and profitability.

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*If we or our brand names fail to maintain a positive reputation, many aspects of our business and our business prospects 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:

- gain access to, and for our products to be perceived favorably by, medical institutions and healthcare professionals that drive and affect patient demand for pharmaceutical products in the PRC;
- 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 business 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 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:

- misuses of our trademarks by our connected persons who are licensed to use such trademarks;
- the effects of counterfeit products purporting to be our products or the third-party products which we sell and/or promote;
- adverse associations with our products or the third-party products which we sell and/or promote, including with respect to their efficacy or side effects;
- improper or illegal conduct, or the perception or allegation of illegal conduct, by our employees, distributors, suppliers and third-party promoters, whether or not authorized by us;
- adverse publicity that is associated with us, our products, the third-party products which we sell and/or promote or our industry, whether founded or unfounded; and
- lawsuits and regulatory investigations against us, our employees, distributors or third-party promoters, or otherwise relating to our products or industry.

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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, healthcare professionals, regulators and patients, our business and results of operations may be materially and adversely affected.

In addition, despite our internal guidelines and supervision efforts, our employees, distributors or third-party promoters may fail to follow such guidelines, which may adversely affect our sales and reputation. For example, our employees, distributors or third-party promoters may fail to provide accurate and complete information about our products, as a result of which hospitals, other medical institutions, doctors and patients may misunderstand or misuse our products. 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.

***If our products, or the third-party products that we sell and/or promote, are not produced to the necessary quality standards, our business and reputation could be harmed, and our revenue and profitability could be adversely affected.***

Our products and manufacturing processes are required to meet certain quality standards. We have established a quality control management system and standard operating procedures to help prevent quality issues in respect of our products. See “Business – Quality Control” for details of our quality control management system and standard operating procedures. Despite these quality control efforts, we may not be able to detect or cure product defects as a result of a number of factors, many of which are outside our control, including:

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

In addition, when we expand our production capacity in the future, we may not be able to ensure consistent quality between our products manufactured in our existing and new facilities without incurring substantial costs. Furthermore, if we acquire other pharmaceutical companies, we may not be able to immediately ensure that their production facilities and processes will meet our own quality standards.

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

In addition, we have limited control over the quality of the third-party products that we sell and/or promote. If such products are found defective, or are otherwise not produced to the necessary quality standards, our reputation and our business could be harmed, and we could be potentially exposed to liability, which may materially and adversely affect our results of operations.

***If our products cause, or are perceived to cause, severe side effects, our revenue and profitability could be materially and adversely affected.***

Our products may cause undesirable or unintended side effects as a result of a number of factors, many of which are outside our control. These factors include potential side effects not revealed in clinical trials, unusual but severe side effects in isolated cases, defective products not detected by our quality control 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 an international institution, such as the WHO, determines that products containing the same or similar pharmaceutical ingredients as our products' could cause or lead to severe side effects.

If our products cause, or are perceived to cause, severe side effects, we may face a number of consequences, including:

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

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## RISK FACTORS

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- stricter and more frequent regulatory inspections of our production facilities and products;
- removal of relevant products from any medical insurance catalogs, provincial lists of special medications related to the severe diseases insurance or the National Essential Drug List, as applicable;
- inability to participate in the centralized tender process; and
- exposure to lawsuits and regulatory investigation relating to the relevant products that result in liabilities, fines or penalties.

The occurrence of any of the above could materially and adversely affect our business, results of operations and financial condition.

***We may be subject to product liability claims, which could expose us to costs and liabilities and adversely affect our operations and reputation.***

The nature of our business exposes us to the risk of product liability claims that is inherent in the developing, manufacturing and marketing of pharmaceutical products in the PRC and other jurisdictions in which we sell and/or promote pharmaceutical products, including products manufactured by third-party pharmaceutical companies. Such claims may arise if any of the products we sell and/or promote are deemed or proven to be unsafe, ineffective, defective or contaminated or if we are alleged to have engaged in practices such as improper or insufficient labeling of products or providing inadequate warnings or insufficient or misleading disclosures of side effects. Using product candidates in clinical trials also exposes us to product liability claims. 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.

PRC laws and regulations currently do not require us to, nor do we, maintain any product liability insurance to cover damages that may arise from product liability claims. If a product liability claim is brought against us, it may, regardless of merit or outcome, result in damage to our reputation, breach of contract with our customers, decreased demand for our products, costly litigation, product recalls and loss of revenue and capability to commercialize our products. If we are unable to defend ourselves against such claims in the PRC, 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 the products we sell and/or promote are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Other jurisdictions in which our products are, or may in the future be, sold, in particular in developed markets, 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. 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.

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## RISK FACTORS

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*If we fail to conduct effective promotion or maintain a qualified sales force, our sales 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, other medical institutions and pharmacies and promote new products in the future. However, we cannot assure you that our promotion and marketing activities will be adequate to support our future growth. If we are unable to increase or maintain the effectiveness and efficiency of our promotion and marketing activities, our sales and business prospects could be adversely affected.

In particular, our promotion and marketing efforts are anchored by academic marketing, through which our sales and marketing personnel promote our products to, and raise awareness and knowledge of our products and product candidates among, healthcare professionals, hospitals, other medical institutions and pharmacies. Therefore, the success of our marketing strategies depends on our ability to attract, motivate and retain a sufficient number of qualified sales and marketing personnel that possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, sufficient expertise in the relevant therapeutic areas and products as well as sufficient promotion and communication skills. Competition for experienced promotion, sales and marketing personnel is intense. If we are unable to attract, train and retain a sufficient number of qualified promotion, sales and marketing personnel, the sales volume of our products could be adversely affected and we may be unable to continue to extend our market penetration and coverage of hospitals, other medical institutions and pharmacies as contemplated.

Moreover, under our agreements with third-party pharmaceutical companies to which we provide promotion services and/or from which we source certain pharmaceutical products that we sell and/or promote, and our collaboration agreements with some of our R&D partners, we are generally subject to annual minimum purchase, sales and/or promotion requirements specified in the relevant agreements. During the Track Record Period, there were two instances where we failed to meet the annual minimum requirements specified in the relevant promotion agreement or the distribution agreement (with promotion clause included) with third-party pharmaceutical companies. Although the third-party pharmaceutical companies are entitled to terminate the relevant agreements pursuant to the terms thereof, our business relationships continued in spite of such instances. For the first instance, we are in the process of finalizing the terms of compensation with the third-party pharmaceutical company and expect to pay RMB5.0 million for the shortfall, for which amount we have made provision in full. For the second instance, both parties have agreed to a reduced annual minimum requirement together with termination of our promotion rights in relation to certain specified medical institutions which our sales and distribution network did not effectively cover. Therefore, these instances did not have any material adverse effect on our business, results of operations and financial condition. However, we cannot assure you that such event will not happen in the future. In the event of our failure to meet any such requirement, we may face negative consequences, including compensation for the shortfall, adjustment to the scope of our promotion, distribution or commercialization rights and termination of agreements, which may materially and adversely affect our business, results of operations and financial condition.



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## RISK FACTORS

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***If we fail to maintain, expand and optimize an effective distribution network for our products, our sales and business prospects could be materially and adversely affected.***

As of June 30, 2020, we had a network of 616 distributors, which we rely on to distribute a substantial portion of our products. Our ability to maintain and grow our sales depends on our ability to manage, expand and optimize a distribution network that timely delivers our products across and outside of China where market demand for our products is generated through our promotion and marketing activities, or otherwise. However, our distributors are third parties over whom we have limited control and we cannot assure you that our distributors will always distribute our products in an effective manner. For example, if our distributors distribute our products outside their designated distribution areas as provided under their distribution agreements with us, the effectiveness of our distribution network could be adversely affected. Since our distributors generally do not sell our products on an exclusive basis, our products also compete with similar products from our competitors sold by our distributors.

In line with industry practice in China, we typically enter into distribution agreements with our distributors for a term of one year, which requires us to continually review distribution agreements across our distribution network in order to maintain the relationship with our distributors. As our existing distribution agreements expire, we may not be able to renew these agreements with our distributors on commercially acceptable terms or at all. Our distributors may elect not to renew their distribution agreements with us or otherwise terminate their business relationships with us for various reasons, including in the event that PRC pricing regulations or other factors substantially reduce the margins they can obtain through the resale of our products. In addition, we may not be able to establish business relationships with additional distributors to support the continued growth of our business. 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 business, results of operations and financial condition could be materially and 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 in our distribution agreements, our business, financial condition and results of operations may be materially and adversely affected.

***Development of new products, in particular innovative drugs, is time-consuming and costly and the outcome is uncertain. If we fail to develop and commercialize new products, our business prospects could be adversely affected.***

Our long-term competitiveness depends on our ability to enhance our existing products, diversify our product offering and develop and commercialize new products through our research and development activities. The development process of pharmaceutical products, in particular innovative drugs, is time-consuming and costly, and there can be no assurance that our research and development activities will enable us to successfully develop new products.

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## RISK FACTORS

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There is an inherent risk of failure for each of our product candidates. We cannot predict when or if any of our product candidates will prove effective and safe for humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, our product candidates must complete pre-clinical studies and we must then conduct extensive clinical trials to demonstrate the safety and efficacy of our product 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. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Since relatively few research and development projects in the pharmaceutical industry produce a commercially viable product, a product candidate that appears promising in the early phases of research and development may fail to be successfully commercialized for a number of reasons. For example:

- regulators, 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, to conduct additional clinical trials or we may decide to abandon product development projects;
- the number of patients required for clinical trials of our product 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;
- we may fail to conduct a companion diagnostic test to identify patients who are likely to benefit from our product candidates;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research 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 product candidates may be greater than we anticipate;
- supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

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## RISK FACTORS

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- we may fail to obtain approvals for intended indications from relevant regulatory bodies, such as the NMPA;
- third parties may hold proprietary rights, such as patent rights related to our product candidates 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 research and development process more time-consuming and costly. Please see “– We are subject to changing legal and regulatory requirements in the PRC pharmaceutical industry, and new laws, rules and regulations may adversely affect our profitability or impose additional compliance burdens on us.”

New pharmaceutical products must complete clinical trials and obtain the NMPA’s approval before they can be produced, 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. 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, therefore restricting its market size. Meanwhile, even if such products can be successfully commercialized, they may not achieve the level of market acceptance that we expect. Any of these circumstances could adversely affect our business, results of operations and growth prospects.

***We experienced a decrease in our profitability for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. There can be no assurance that our profitability will not continue to decrease or we will be able to improve our profitability in the short-term.***

Our net profit decreased by 59.9% from RMB461.0 million for the six months ended June 30, 2019 to RMB184.8 million for the six months ended June 30, 2020. The decrease was primarily due to (i) the outbreak of COVID-19 which resulted in a decrease in demand for pharmaceutical products in general, according to Frost & Sullivan; (ii) a decrease in sales of Bicun as a result of its exclusion from the latest version of the NRDL which came into force on January 1, 2020; (iii) an increase in research and development costs to support our continued R&D efforts; (iv) a decrease in sales of Endostar as a result of the decrease in its pricing level attributable to the national medical insurance pricing negotiation process for renewing its inclusion in the latest version of the NRDL; and (v) a decrease in sales of Softan and Jiebaili as Softan did not win in the bidding processes under the centralized volume-based drug procurement schemes, while Jiebaili was ineligible for bidding because it had yet to pass the consistency evaluation. Please see “Financial Information – Recent Developments on Our Financial Performance” for more details.

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## RISK FACTORS

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There can be no assurance that the above factors will cease affecting, or any additional factors will not in the future affect, our business and profitability. In particular, we have been investing heavily on our research and development efforts. For the years ended December 31, 2017, 2018 and 2019 and the six months ended June 30, 2020, our research and development expenses accounted for 5.5%, 9.9%, 14.2% and 23.6%, respectively, of our total revenue for the same periods. We need to continue to invest significant resources, including financial resources, in research and development activities to enhance our existing products, diversify our product offering and develop and commercialize new products. As a result, we expect that our research and development expenses will continue to increase.

If we are not able to improve our profitability in the short-term, our financial performance, liquidity, financial position, business operations and prospects may be adversely affected and the investors will be exposed to high risk of investment in our Company.

***Our CAR T-cell therapy candidates and TCR T-cell therapy candidates represent emerging approaches to cancer treatment that face significant challenges and hurdles in research and development, regulatory compliance, commercialization and clinical use.***

We are currently collaborating with certain collaboration partners on the development and commercialization of three CAR T-cell therapy candidates, please see “Business – Our Product Portfolio – Our Product Pipeline – Innovative Product Pipeline – Oncology Product Candidates – 3. CD19 CAR T-cell Therapies” and “Business – Our Product Portfolio – Our Product Pipeline – Innovative Product Pipeline – Oncology Product Candidates – 4. BCMA CAR T-cell Therapy” for more details. We are also collaborating with a collaboration partner on the development and commercialization of a TCR T-cell therapy candidate. Development of such product candidates is still at early stage. As with other targeted therapies, off-tumor or off-target activity could delay development or require us to reengineer or abandon a particular product candidate. Because CAR T-cell therapies and TCR T-cell therapies represent a relatively new field of cell therapy and cancer treatment generally, developing and commercializing the relevant product candidates subject us to a number of risks and challenges, including:

- obtaining regulatory approval for CAR T-cell therapy candidates or TCR T-cell therapy candidates, as the NMPA and other regulatory authorities have limited experience with CAR T-cell therapies and TCR T-cell therapies for cancer;
- developing and deploying consistent and reliable processes for engineering a patient’s T cells ex vivo and infusing the engineered T cells back into the patient;
- preconditioning patients with chemotherapy prior to infusing the CAR T-cell therapy candidates or TCR T-cell therapy candidates back into such patients, which may increase the risk of adverse side effects of such product candidates;

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## RISK FACTORS

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- triggering cytokine release syndrome and neurotoxic side effects during the in vivo amplification of CAR T-cell therapy candidates or TCR T-cell therapy candidates and in the process of killing tumor cells;
- sourcing clinical and, if approved, commercial supplies of the materials used to manufacture CAR T-cell therapy candidates or TCR T-cell therapy candidates;
- developing programming modules with the desired properties, while avoiding adverse reactions;
- creating viral vectors capable of delivering multiple programming modules;
- developing a reliable and consistent vector and cell manufacturing process;
- establishing manufacturing capacity suitable for the manufacture of CAR T-cell therapy candidates or TCR T-cell therapy candidates in line with expanding enrollment in our clinical studies and our projected commercialization requirements;
- achieving cost efficiencies in the scale-up of our manufacturing capacity;
- developing protocols for the safe administration of CAR T-cell therapy candidates or TCR T-cell therapy candidates;
- educating healthcare professionals regarding our CAR T-cell therapy candidates and TCR T-cell therapy candidates and the potential side effect profile thereof;
- establishing integrated solutions in collaboration with specialty treatment centers in order to reduce the burdens and complex logistics commonly associated with the administration of T cell therapies;
- establishing sales and marketing capabilities to successfully launch and commercialize CAR T-cell therapy candidates or TCR T-cell therapy candidates if and when we obtain the required regulatory approvals, and risks associated with gaining market acceptance of novel therapies if we receive approval; and
- the availability of coverage and adequate reimbursement for our novel and personalized therapies in connection with commercialization of any approved CAR T-cell therapy candidates or TCR T-cell therapy candidates.

We may not be able to successfully develop our CAR T-cell therapy candidates or TCR T-cell therapy candidates in a manner that will yield products that are safe, effective, scalable or profitable, nor can we assure you that we will be able to successfully commercialize such product candidates.

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## RISK FACTORS

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Additionally, because our CAR T-cell therapy candidates and TCR T-cell therapy candidates involve the genetic modification of patient cells *ex vivo*, we are subject to additional regulatory challenges and risks, including:

- regulatory requirements governing genetic and cell therapy products have changed frequently and may continue to change in the future. As of June 30, 2020, only two CAR T-cell therapy products that involve the genetic modification of patient cells have been approved outside of China, and none have been approved in China. As of June 30, 2020, none of TCR T-cell therapy products have been approved in China and abroad;
- genetically modified products in the event of improper insertion of a gene sequence into a patient's chromosome could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells;
- although our viral vectors are not able to replicate, there is a risk with the use of retroviral or lentiviral vectors that they could lead to new or reactivated pathogenic strains of virus or other infectious diseases; and
- the FDA recommends a 15-year follow-up observation period for all patients who receive treatment using genetic therapies, and the NMPA also requires a long-term follow-up observation period for patients who receive treatment using cell therapies. Therefore, we need to adopt an observation period for our product candidates.

Moreover, public perception and awareness of cell therapy safety issues may adversely influence the willingness of subjects to participate in clinical trials of our product candidates, or if approved, of physicians to prescribe our products. Healthcare professionals and medical institutions often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Treatment centers may not be willing or able to devote the personnel and establish other infrastructure required for the administration of CAR T-cell therapies or TCR T-cell therapies. Physicians may not be willing to undergo training to adopt these novel and personalized therapies, may decide the therapies are too complex to adopt without appropriate training and may choose not to administer the therapies. Based on these and other factors, medical institutions may decide that the benefits of these new therapies do not or will not outweigh their costs.

***If we fail to achieve the product development milestones as disclosed in this prospectus or subsequent public disclosures, it could adversely affect the price of our Shares and our business prospects.***

We disclose in this prospectus our expectations or targets for the timing of certain milestones associated with our product development projects, including the anticipated regulatory approval for the manufacture and sale of our product candidates. After the Listing, as a publicly listed company, we may continue to make such disclosures of our expectations. However, the successful implementation of our product development projects is subject to

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significant business, economic and competitive uncertainties and contingencies, including, product development risk, the availability of funds, competition and grant of relevant approvals and permits, which we will re-evaluate from time to time based on the government regulations and policies as well as the continued growth of the pharmaceutical market.

The actual timing for achieving product development milestones could vary significantly from our expectations due to a number of factors, many of which are outside our control, including delays or failures in our pre-clinical studies or clinical trials, failure to maintain, renew or establish new relationships with actual or potential research and development partners, the approval process for new pharmaceutical products in the PRC and the uncertainties inherent in that regulatory approval process and delays in achieving manufacturing or marketing arrangements sufficient to commercialize our product candidates. There can be no assurance that our pre-clinical studies or clinical trials will be completed as planned or at all or that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the launch of any of our products candidates. If we fail to achieve one or more of these expected product development milestones as planned, the price of our Shares and our business prospects may be adversely affected.

According to the “Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation” (《關於鼓勵藥品創新實行優先審評審批的意見》) (the “**Prioritized Evaluation and Approval Opinions**”), which was promulgated and implemented on December 21, 2017 by the NMPA, the NMPA conducts priority review and approval for new drug registration applications that meet specific requirements.

The Prioritized Evaluation and Approval Opinions has been replaced by three documents issued by the NMPA on July 7, 2020, namely, the “Evaluation Procedures for Breakthrough Therapeutic Drugs (Trial)” (《突破性治療藥物審評工作程序(試行)》), the “Evaluation and Approval Procedures for Conditional Approval of Drug Application (Trial)” (《藥品附條件批准上市申請審評審批工作程序(試行)》) and the “Prioritized Evaluation and Approval Procedures for Drug Approval (Trial)” (《藥品上市許可優先審評審批工作程序(試行)》). These newly-issued documents stipulate that for innovative or imported drug candidates intended for prevention or treatment of fatal diseases, applicants may apply for the evaluation procedures for breakthrough therapeutic drugs before the initiation of phase III clinical trials, provided that there are no effective prevention or treatment options for such fatal diseases or such drug candidates demonstrate superior clinical advantages over the existing prevention or treatment options. In addition, these newly-issued documents provide that applicants may apply for the prioritized evaluation and approval procedures for drug candidates with apparent clinical value. There can be no assurance that any of our product candidates, will be eligible to file for special evaluation and approval procedures or such procedures may lead to faster development or regulatory review or approval process. Moreover, even if any of our product candidates are eligible to file for special evaluation and approval procedures, such designation may not increase the likelihood that our product candidates will receive regulatory approval and we cannot assure you that we will be able to maintain these designations, in which case our business and results of operations may be materially and adversely affected.

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## RISK FACTORS

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*We rely on third parties to monitor, support and/or conduct pre-clinical studies and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual obligations or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.*

We have relied on and plan to continue to rely on third-party CROs, hospitals and clinics which are beyond our control to monitor, support and/or conduct pre-clinical studies and clinical trials of our product candidates. Nevertheless, we are responsible for ensuring that each of such studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs, hospitals and clinics does not relieve us of our regulatory responsibilities. We, our CROs and our investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA and other comparable regulatory authorities for all of our product candidates. If we or any of our CROs or investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter any such challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition and prospects.



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## RISK FACTORS

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*We have entered into collaboration arrangements for the development and commercialization of our product candidates, and may continue to form or seek collaborations in the future, and we may not realize the benefit of such collaborations.*

As an essential component of our research and development model, we have entered into long-term collaboration arrangements with leading domestic and international pharmaceutical companies and biotechnology companies to co-develop or in-license innovative and high end generic drug candidates that have high potential for commercialization in China. Please see “Business – Research and Development – Collaboration with Research and Development Partners.” Any of these relationships may require us to incur non-recurring and other charges or increase our near and long-term expenditures.

In addition, we face significant competition in seeking appropriate research and development partners and the negotiation process is time-consuming and complex. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For any product candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization projects based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our product candidates;

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- collaborators may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaboration with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of current or future collaborations if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a research and development collaboration, we will achieve the revenue or specific net income that justifies such collaboration. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate revenue, which would harm our business prospects, financial condition and results of operations.

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## RISK FACTORS

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*If our employees, distributors or third-party promoters engage, or are perceived to engage, in misconduct or breaches, including corrupt practices, inappropriate promotion of our products or the third-party products that we sell and/or promote, or leakage of confidential information, our business and reputation could be harmed and we could be exposed to regulatory investigations, penalties or other negative consequences.*

We have limited control over the interactions our employees, distributors and third-party promoters have with hospitals, other medical institutions, pharmacies and healthcare professionals, and they may try to increase sales volumes of our products or the third-party products through means that constitute violations of anti-corruption and other related laws in the PRC and other relevant jurisdictions. There have been several instances of corrupt practices in the pharmaceutical industry recently, including, among other things, acceptance of kickbacks, bribes or other illegal gains or benefits by hospitals, other medical institutions and healthcare professionals from pharmaceutical manufacturers, distributors and retail pharmacies in connection with the procurement or prescription of pharmaceutical products. Any allegations of such behavior against us, our employees, distributors or third-party promoters or the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation, sales activities and business prospects. There were in the past some limited instances of allegations of misconduct against us, which, although were proven to be untrue, had an adverse effect on our reputation and sales. For example, in December 2016, the local healthcare administrative authority ordered the temporary suspension of sales of Softan (10 mg) to public medical institutions in Hunan Province due to an alleged kickback arrangement. Sales of Softan (10 mg) to public medical institutions in Hunan Province were permitted to be resumed in July 2018 pursuant to a notice by the local healthcare administrative authority and neither we nor our relevant employee was subject to the imposition of any penalty or subject to notification of any breach in respect of non-compliant sales practices. If our employees, distributors or third-party promoters engage in corrupt or other improper conduct that result in violation of applicable anti-corruption laws in the PRC or other jurisdictions, our reputation could be severely harmed, and our sales activities could be materially and adversely affected.

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, distributors or third-party promoters from engaging in such activities in the past or in the future. We could be held liable for actions taken by our employees, distributors or third-party promoters, which could expose us to regulatory investigations, penalties, revocation of operating licenses and permits, and even criminal liabilities. Actions taken by PRC regulatory authorities or the courts that provide an interpretation of 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.

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## RISK FACTORS

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Pursuant to the “Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry” (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the NHFPC on December 25, 2013, and came into effect on March 1, 2014, if we are involved in criminal, investigational or administrative procedures for commercial bribery, we will be listed in the adverse records of commercial bribery by the relevant government authorities, as a result of which, for two years from the date the list of adverse records of commercial bribery is published, (i) our products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within the relevant provinces, and (ii) the scores of our products in the centralized tender processes of public medical institutions or medical and health institutions receiving financial subsidies in other provinces will be reduced. Furthermore, if we are listed in the adverse records of commercial bribery 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 from the date the list of adverse records of commercial bribery is published. See “Regulatory Overview – Laws and Regulations Relating to Anti-unfair Competition” for more details.

In addition, we are required to comply with anti-corruption and confidentiality requirements in our agreements with our business partners, including certain collaboration partners and manufacturers of third-party products. Any breach of such anti-corruption or confidentiality requirements by us may result in negative consequences, including payment of penalties and termination of agreements, which could have a material adverse effect on our business, financial condition, results of operations and profitability.

Moreover, our business may be materially and adversely affected if our business partners breach confidentiality requirements, or if our employees breach the non-disclosure, non-compete and non-solicitation clauses in their employment agreements.

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

A substantial majority of our revenue has been, and in the near future will continue to be, generated by sales of products produced at our five production facilities. The continued operation of our production facilities and our production safety can be substantially interrupted and materially and adversely due to a number of factors, many of which are outside our control, including fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars or other natural disasters, as well as loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities or their vicinity and regulatory changes.

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## RISK FACTORS

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If the operation of any of our production facilities is substantially disrupted, we may not be able to replace the equipment or inventories at such facility or secure a replacement facility or a third-party contractor to continue our production in a legal, timely and cost-effective manner or at all. Although we maintain property insurance for our production facilities and equipment, we do not maintain business interruption insurance, and the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to any of our production facilities. Problems may also arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of our existing production facilities, including changes in production facilities and limits to production capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. As a result, disruption to any of our production facilities or any problem in manufacturing our products may prevent us from fulfilling our contract obligations or meeting market demand for our products, and adversely affect our business, revenue and profitability.

*If we fail to increase our production capacity, our business prospects could be adversely affected.*

We plan to increase our production capacity by constructing new production facilities, new production workshops and new production lines. Please see “Business – Production – Production Facilities – Expansion Plan” for more details. However, our ability to successfully implement our expansion plan for increasing our production capacity is subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain the requisite permits, licenses and approvals for the construction and operation of the new production facilities, production workshops and production lines, the risk of construction delays and delays in equipment procurement, as well as our ability to timely recruit sufficient qualified staff to support the increase in our production capacity. Consequently, there can be no assurance that we will be able to increase our production capacity in the manner we contemplate, or at all. In the event we fail to increase our production capacity, we may not be able to capture the potential growth in demand for our products, or to successfully commercialize the product candidates in our pipeline, each of which could adversely affect our results of operations and business prospects. Moreover, our plans to increase our production capacity require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could adversely affect the return on our expenditures. Our expansion plans may also increase our operating costs, such as higher staff costs as well as depreciation and utility costs, which may adversely affect our results of operations and financial condition.

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## RISK FACTORS

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***Failure to maintain optimal inventory levels could increase our operating costs or lead to unfulfilled customer orders, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.***

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 accurately.

We have an extensive product portfolio and maintain significant 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 have 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 adverse effect on our business, financial condition, results of operations and prospects.

***We depend on the supply of certain raw materials and pharmaceutical products, and a decrease in the supply, or an increase in the cost, of raw materials, or any shortage or delay in the supply of pharmaceutical products, could severely disrupt our business as well as materially reduce our revenue and profit.***

We source certain of our raw materials, including APIs and packaging materials, from third-party suppliers. Please see "Business – Production – Raw Material Suppliers and Procurement." Cost of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period. We cannot assure you that we will be able to renew our agreements with our existing suppliers when they expire or to enter into new supplier relationships to support the continued growth of our business. In addition, we typically do not enter into long-term supply agreements with raw material suppliers and as a result are vulnerable to supply shortages and fluctuations in market prices.

The availability and prices of these raw materials may be impacted for various reasons that are beyond our control, such as unexpected increases in demand for such raw materials from producers of substitute products, adverse weather conditions, occurrence of natural disasters, regulatory actions, deteriorating financial conditions or cessation of business of the suppliers and labor shortages. In the event that any of our suppliers fails to continue to supply us with sufficient quantities of raw materials of an acceptable quality in the future, we may be

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## RISK FACTORS

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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. Also, the market prices of raw materials may be subject to significant fluctuations. 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.

Moreover, we rely on third-party pharmaceutical companies to which we provide promotion services and/or from which we source third-party products to manufacture and supply certain pharmaceutical products that we sell and/or promote. In addition, pursuant to the collaboration arrangement with some of our R&D partners, such as BMS and Amgen, upon obtaining applicable regulatory approvals, they will manufacture and supply the relevant products to us for our commercialization. We have limited control over the manufacture process, delivery arrangement and supply chain management of these third-party pharmaceutical companies and R&D partners. In particular, the occurrence of any industry downturn, natural disaster or catastrophic event could interrupt their manufacturing or delivery of the relevant products, resulting in inadequate or delayed supply to us or to our designated distributors. Any potential inadequate or delayed supply may force us or our designated distributors to deliver the relevant products on a delayed basis, cancel product orders or cease product offering. Consequently, our results of operations could be adversely affected, our reputation and our relationships with our distributors and direct sales customers could be harmed, and we could be potentially exposed to litigation and damage claims. Besides, our business may be materially and adversely affected if these third-party pharmaceutical companies or R&D partners distribute the relevant products in our designated geographic areas in violation of the terms of our agreements with them.

***We may not be able to successfully complete any further acquisitions or enhance post-acquisition performance, which could adversely affect our business prospects.***

We may make acquisitions when appropriate opportunities arise in the future. However, our ability to successfully consummate any future acquisitions is subject to various risks and uncertainties, including:

- failure to identify suitable acquisition targets or have to engage in intense competition for attractive acquisition targets, which may make it difficult to complete such acquisitions on commercially acceptable terms or at all;
- failure to obtain sufficient financing on acceptable terms or at all, to fund such acquisitions; and
- failure to obtain or secure regulatory approvals and third-party consents necessary to consummate such acquisitions.

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## RISK FACTORS

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Even if we are able to consummate any acquisitions, our ability to grow our business through any recently completed or future acquisitions remains subject to further risks and uncertainties which could materially and adversely affect our business, financial condition and results of operations, including that:

- we may fail to successfully integrate the acquired businesses with our existing business and operations;
- we may fail to effectively manage a larger, growing business, operating in new therapeutic areas or geographic regions;
- the acquired businesses do not provide us with the intellectual property rights, technology, R&D capability or production capability we had anticipated;
- the acquired businesses are subject to unforeseen or hidden liabilities; and
- the acquired businesses do not generate the revenue and profitability we had anticipated.

If we are unable to consummate acquisitions and successfully grow our business through any future acquisitions, our business and prospects could be adversely affected.

Furthermore, the process of pursuing and consummating acquisitions as well as integrating and managing acquired businesses, whether or not successful, could divert our resources and management attention from our existing business and impair our ability to successfully manage and grow our business organically.

***If counterfeits of our products become available in the market, it could negatively affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims.***

Certain products distributed or sold in the pharmaceutical markets in the PRC and overseas may be manufactured without proper licenses or approvals or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as the PRC, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products, including counterfeits of our products.



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Since counterfeit pharmaceutical products in many cases are very similar in appearance to the authentic products but are generally sold at lower prices, counterfeits of our products can quickly erode our sales volume of the relevant products. Moreover, counterfeit products may or may not have the same chemical composition as our products do, 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. The appearance of counterfeit pharmaceutical products, products of inferior quality and other unqualified products in the pharmaceutical market from time to time may reinforce the negative image in general of all pharmaceutical products manufactured in the PRC or other relevant markets among consumers, and may harm the reputation and brand names of companies like us, particularly in overseas markets. Similarly, consumers may buy counterfeits of products that are in direct competition with our products, which may materially and adversely affect the sales volumes of our products and adversely affect our business, financial condition, results of operations and prospects.

Although certain products available on the market might be similar in appearance to our products, we are not aware of any instances of counterfeits of our products. However, we cannot assure you that we will be able to prevent occurrences of counterfeits of our products or such counterfeits, if any, will not have a material adverse effect on our business, results of operations and financial condition.

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 materially and adversely affect our reputation, business, results of operations and financial condition.

***Failure 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, which may have a material adverse impact on our business and results of operations.***

Our intellectual property, including but not limited to our patents, trademarks, trade secrets and know-how, is critical to our success. Please see “Business – Intellectual Property Rights” and “Appendix V – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual property rights of our Group” for more details about our material intellectual property rights. We protect our intellectual property rights by filing patent and trademark applications, securing pharmaceutical regulatory protection, establishing and enforcing confidentiality contractual obligations, relying on trade secrets or employing a combination of these methods. However, these measures may not be adequate for a number of reasons, including those described below, some of which are beyond our control.

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## RISK FACTORS

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We apply for patents for all of our innovative pharmaceutical products. There are a number of risks and uncertainties related to our patents and patent applications:

- The process of seeking patent protection in the PRC can be lengthy and expensive, and there is no assurance that any of our pending or potential future patent applications will mature into issued patents, or that such patents, if issued, will provide us with adequate proprietary protection or competitive advantages;
- The PRC has adopted a first to file system for patent applications, under which 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 before we are able to obtain such patent;
- Our existing patents may become invalid or unenforceable for a number of reasons, 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 impact on the sales volumes and pricing levels for such products and our ability to successfully commercialize such product candidates;
- The patents and patent applications for certain products in our product portfolio and certain product candidates we intend to develop do not cover the underlying APIs. 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 APIs. In addition, patents covering preparation methods and formulation may not create sufficient technical barriers to prevent other pharmaceutical developers from developing substitute products; and
- The patents that we hold are for a finite duration. Following the expiration of the relevant patents, our existing or future competitors may be able to develop and introduce substitute products to our 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.

We also rely on trademarks, trade secrets and other intellectual property rights to protect our product candidates, products and technologies. However, our efforts to defend our intellectual property rights may be unsuccessful and we may not have adequate remedies for any breach.

Moreover, intellectual property rights and confidentiality protection in China may not be as effective as in the United States or other developed countries, due to, among other causes, lack of procedural rules for discovery and evidence, low damage awards and lack of judicial independence. Detecting and policing unauthorized use of proprietary technology are difficult

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## RISK FACTORS

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and expensive, and we might need to resort to litigation to enforce or defend our intellectual property rights or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of PRC courts in handling intellectual property litigation vary, and outcomes may be unpredictable. Furthermore, such litigation may require significant expenditures and management efforts. An adverse determination in any such litigation could materially impair our intellectual property rights and may harm our business, prospects and reputation.

If we fail to adequately protect our intellectual property for any of the above or other reasons, competitors may be able to imitate or copy our products, use our technologies and erode or negate any competitive advantages we may have, which could harm our business and ability to achieve profitability.

***We may become subject to intellectual property infringement claims, which could divert our management's attention, expose us to substantial liability, harm our reputation, limit our research and development or other business activities and/or impair our ability to commercialize our product candidates.***

Our commercial success depends significantly on our ability to develop, manufacture, market and sell pharmaceutical products and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property 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 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 or other relevant technology. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any product candidates we may develop.

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 have received in the past, and 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 product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents.

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## RISK FACTORS

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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, one or more of the following may occur:

- we may have to reformulate the affected product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very costly and time-consuming;
- we may be forced to discontinue production and sales of the affected product(s) or cease developing and commercializing the affected product candidate(s); and
- we may 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.

Moreover, some of our competitors are larger than we are and have substantially greater resources than we do. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research projects, in-license needed technologies, or enter into strategic partnerships that would help us bring our product 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. If any of the foregoing events occurs, our business may be materially and adversely affected.

***We are subject to environmental regulations; if we fail to comply with such regulations or such regulations change, it may impair our ability to conduct our business and we may be exposed to liability and potential costs for environmental compliance.***

Our pharmaceutical manufacturing process involves the handling, production and use of substances and compounds that may be considered toxic or hazardous within the meaning of environmental laws. We are subject to PRC laws, rules and regulations concerning environmental protection, including the discharge of effluent water and solid waste as well as the disposal of hazardous substances during our manufacturing processes, and may become subject to similar laws, rules and regulations in other jurisdictions in the future. In addition, we are required to obtain clearances and authorizations from relevant PRC government authorities for the treatment and disposal of such discharge. The costs for complying with

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## RISK FACTORS

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existing and future environmental laws, rules and regulations, and the liabilities which may potentially arise from the discharge of effluent water and solid waste as well as the disposal of hazardous substances, may increase our total costs and adversely affect our profitability. There can be no assurances that we will be able to comply fully at all times with applicable environmental laws, rules and regulations. Any violation of these laws, rules or regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our production facilities and obligations to take rectification measures, which in turn, may materially and adversely affect our business, financial condition and results of operations. We may face civil liability for any alleged personal injury or property damage due to exposure to compounds or other hazardous substances at our production facilities or compounds which we otherwise produce or handle. Such claims can be substantial and could in the future materially and adversely affect our business, results of operation and financial condition.

Furthermore, the PRC government or the governments in other jurisdictions in which we operate may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade or supplement our pollution control equipment, take additional protective and other measures against potential contamination or injury caused by hazardous materials, or make operational changes to limit any adverse impact or potential adverse impact on the environment. If these costs become prohibitively expensive, we may be forced to curtail or cease operation of certain of our production facilities. In addition, if we become subject to any significant environmental-related liabilities, it could adversely affect our business, results of operations and financial condition.

***If we become a party to litigations, legal disputes, claims or administrative proceedings, such involvement may divert our management's attention and result in costs and liabilities and damage our reputation.***

We may from time to time become a party to various litigations, legal disputes, claims or administrative proceedings arising in the ordinary course of our business. Ongoing litigations, legal disputes, claims or administrative proceedings may divert our management's attention and significantly consume our other resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings which initially do not appear to be of material importance may escalate due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved.

Negative publicity arising from litigations, 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 monetary damages, assume other liabilities and even to suspend or terminate the related business. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

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## RISK FACTORS

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*Our overseas investments may be subject to laws, regulations and policies, as well as changes thereof, in the PRC and the corresponding jurisdictions, which may materially and adversely affect our business, financial condition, results of operations and prospects.*

In the United States, the Committee on Foreign Investment in the United States (the “CFIUS”) has broad authority to review foreign investments to assess whether such investments pose national security risks. If CFIUS identifies national security risks, it is authorized to impose mitigation measures or to recommend to the President that the transaction be blocked. Some foreign investments in U.S. businesses are subject to a mandatory filing requirement, including certain investments in U.S. businesses working with “critical technologies.” The term “critical technologies” means technologies subject to certain U.S. export controls, including “emerging technologies.” Certain biotechnologies are subject to U.S. export controls, and the U.S. Commerce Department is currently engaged in a rulemaking process regarding “emerging technologies” that could result in additional biotechnologies being controlled for export.

In 2019, we established our Boston R&D center in Massachusetts, United States, which primarily focuses on innovative and advanced therapies, particularly cell therapy. Future investments in unaffiliated U.S. businesses may be subject to CFIUS jurisdiction and the mandatory filing requirement. If we determine that a CFIUS filing is not mandatory, it may be advisable to seek CFIUS review of such future investments voluntarily, because transactions within CFIUS jurisdiction that are not cleared by CFIUS are at risk of CFIUS review at any time, including post-closing. If CFIUS were to identify national security concerns with any of our future investments in the United States, CFIUS could impose mitigation conditions or recommend that the President block the transaction. Therefore, our ability to invest in U.S. entities and opportunities to acquire technologies and assets that are material to our business operations may be materially and adversely restricted, and we may fail to benefit from the research and development achievements of our Boston R&D center as contemplated. In addition, the imposition of new U.S. export controls on biotechnologies subject to U.S. jurisdiction may adversely affect our ability to export or transfer technologies developed by our Boston R&D center outside the United States.

In addition, we also have a subsidiary in Finland for the maintenance of our exportation licenses, permits and certificates. Any adverse changes of laws, regulations or policies in such jurisdiction could impose additional operating burdens on us, such as increased staff costs and additional investments, which may adversely affect our ability to operate in such jurisdiction on a commercially reasonable basis. Consequently, our business, results of operations and financial condition could be adversely affected. Our limited experience in overseas markets may also expose us to risks and uncertainties, including risks associated with dealing with laws, regulations, government policies, regulatory regimes and regulatory bodies with which we may be unfamiliar, especially those in connection with tax, labor and insurance.

Moreover, overseas investments of our PRC subsidiaries are also subject to the relevant PRC laws and regulations. If our PRC subsidiaries fail to obtain approvals or make filings, or are otherwise found to be non-compliant with any applicable laws and regulations, they may face warnings, penalties, withdrawal of approvals or filings, suspension of investments and even criminal liabilities, any of which could materially and adversely affect our business, financial condition and results of operations.

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## RISK FACTORS

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*Our business depends substantially on our senior management team and other key personnel, and our business may be adversely disrupted if we lose and are unable to replace their services.*

Our success depends heavily upon the continued services of our senior management team, key research and development personnel and key sales and marketing personnel. In particular, the industry experience, management expertise and contributions of our Executive Directors and other members of our senior management team are crucial to our success. Our research and development personnel 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 sales, marketing and distribution 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.

We do not maintain any key person insurance. If we lose the services of one or more of our key personnel, we may not be able to locate suitable or qualified replacements in a timely manner, or at all, and may incur additional expenses to recruit and train new personnel. Consequently, our business could be severely disrupted, the implementation of our business strategies could be delayed, and our financial condition and results of operations could be materially and adversely affected. In addition, if any member of our key personnel joins a competitor or forms a competing business, we may lose know-how, trade secrets and customers.

Moreover, our future success and ability to continue to grow our business will depend in part on our ability to identify, attract and retain additional qualified personnel. We compete for qualified personnel with other pharmaceutical companies, universities, research institutions and other organizations. Competition for these personnel is intense, and the availability of suitable and qualified candidates in China is limited, which could cause us to offer higher compensation and other benefits in order to attract and retain them, and consequently increase and in turn, materially and adversely affect our financial condition and results of operations. If our recruitment and retention efforts are unsuccessful in the future, our business prospects could be adversely affected.

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

We generally grant credit terms ranging from 30 days to 90 days to our distributors. As of December 31, 2017, 2018 and 2019 and June 30, 2020, our trade and bills receivables were RMB698.0 million, RMB951.3 million, RMB1,336.9 million and RMB1,651.5 million, respectively. The average turnover days of our trade receivables for the same periods were 27.4 days, 33.1 days, 54.9 days and 105.7 days, respectively. If our distributors' cash flows, working capital, financial condition or results of operations deteriorate, they may be unable, or they may otherwise be unwilling, to pay trade receivables owed to us promptly or at all. Any substantial

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defaults or delays by our distributors could materially and adversely affect our cash flows, and we could be required to terminate our relationships with such distributors, which may impair the effective distribution of our products.

***If we do not have access to sufficient funding for the implementation of our strategies and other aspects of our business, our business prospects could be adversely affected.***

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 research and development projects for the expansion and diversification of our product portfolio;
- the funding required to consummate acquisitions and integrate acquired businesses; and
- the capital expenditure required to increase our production capacity and to upgrade and enhance our facilities.

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

We expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources. However, our ability to obtain external financing on commercially reasonable terms, or at all, will depend on a number of factors, many of which are outside our control, including our financial condition, results of operations and cash flows, the economic conditions in the PRC, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. If we cannot obtain sufficient external financing on commercially acceptable terms, or at all, to implement our business strategies and business plans as currently contemplated, we may be required to revise our strategies and business plans, which could adversely affect our business prospects.

***Our insurance coverage is limited; if we experience uninsured losses, it could adversely affect our financial condition and results of operations.***

Our insurance coverage is limited, and we do not maintain product liability insurance or key person insurance. Please refer to “Business – Insurance” for further details of our insurance coverage. If we experience product liability claims or disruptions to our business, we might incur substantial costs and diversion of resources, which may not be fully covered by insurance. In addition, there are certain types of losses, such as losses from war, acts of terrorism, health or public security hazards, earthquakes, typhoons, flooding and other natural disasters, as for which we cannot obtain insurance at a reasonable cost or at all. Should an uninsured loss or a loss in excess of insured limits occur, we could suffer financial losses, lose



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all or a portion of our production capacity, as well as future revenue anticipated to be derived from the manufacturing activities conducted at that property. If we experience uninsured losses or losses in excess of our insurance coverage, it could adversely affect our financial condition and results of operations.

***Preferential tax treatment and financial subsidies we have enjoyed may change or discontinue, which may have an adverse effect on our financial condition and results of operations.***

Our PRC subsidiaries are subject to the statutory EIT rate of 25%, except Hainan Simcere, Shandong Simcere, Wuhu Simcere and Simcere Pharmaceutical. During the Track Record Period, Hainan Simcere, Shandong Simcere, Wuhu Simcere and Simcere Pharmaceutical were recognized as “high and new technologies enterprises” by the local government authorities and thus were entitled to a preferential EIT rate of 15%. Their recognition as “high and new technology enterprises” needs to be renewed in 2020 or 2021, and we cannot assure you that they will be able to successfully renew it in the future.

We have historically received unconditional government subsidies for our technology innovation and contribution to the local economy and conditional government subsidies for the construction and relocation of production facilities as well as for encouragement of our research and development projects. For the years ended December 31, 2017, 2018 and 2019 and the six months ended June 30, 2020, we recorded government grants of RMB52.3 million, RMB47.0 million, RMB65.9 million and RMB32.5 million, respectively, in our consolidated statements of profit or loss. See “Financial Information – Description of Key Statements of Profit or Loss Items – Other Revenue and Other Net (Loss)/Gain” for further details. These financial subsidies have been given at the discretion of the local government authorities.

There can be no assurances that we would continue to enjoy these preferential tax treatment or financial subsidies at the historical levels, or at all. Any change, suspension or discontinuation of these preferential tax treatment and financial subsidies to us could adversely affect our financial condition, results of operations and cash flows.

***The fair value measurement of certain of our assets is subject to significant uncertainties and risks and the fair value change of such assets may materially and adversely affect our results of operations.***

During the Track Record Period, we recorded certain financial assets at fair value through profit or loss, which mainly included investments in short-term structured deposits and wealth management products as well as investments in units in investments funds and equity securities of private companies. Please see “Financial Information – Certain Balance Sheet Items – Financial Assets at Fair Value through Profit or Loss and Trading Securities” for more details. We recorded net realized and unrealized losses on financial assets at fair value through profit or loss of RMB166.5 million in 2017 and net realized and unrealized gains on financial assets at fair value through profit or loss of RMB81.7 million, RMB20.2 million and RMB13.3 million, respectively, in 2018, 2019 and the six months ended June 30, 2020.

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## RISK FACTORS

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The fair value of these assets was determined by various applicable valuation techniques, including, among others, discounted cash flows approach and comparable transactions approach. Major assumptions used in the valuation include discount rate and discount for lack of marketability and changes in these major assumptions could materially affect the respective fair value of these assets. This means that our valuations of relevant financial assets are based on unobservable inputs and our own assumptions about how market participants would price the financial asset in question. Inputs into the determination of fair value of these financial assets require significant management judgment or estimation. Such valuations are inherently uncertain, may fluctuate over short periods of time and may be based on estimates, our determinations of fair value may differ materially from the values that would have been used if a ready market for these financial assets existed. Our financial position and results of operations could be adversely affected if our determinations turn out to be inaccurate.

In addition, the inherent uncertainties and risks associated with investment in investment funds and private companies may affect the fair value of our financial assets. Unsatisfactory results of operations of these investment funds or private companies for a prolonged period, failure to achieve our intended objectives or benefits in making these investments, or other negative market or industry conditions may result in significant decreases in the value of our financial assets, which in turn may materially and adversely affect our results of operations and financial condition.

***Our high gearing ratio, net current liabilities and negative operating cash flow position expose us to liquidity risk.***

During the Track Record Period, we relied significantly on bank borrowings to finance our business operations. We expect that we may continue to do so in the future. As of December 31, 2017, 2018 and 2019 and June 30, 2020, our outstanding bank loans amounted to RMB1,153.1 million, RMB2,057.3 million, RMB2,783.1 million and RMB3,480.4 million, respectively, and our gearing ratio was 74.0%, 148.1%, 198.7% and 201.1%, respectively. Our high gearing ratio may adversely affect our liquidity and business operations, including but not limited to (i) increase our vulnerability under adverse economic or industry condition; (ii) limit our flexibility in planning for, or reacting to, changes in our business or in the industry in which we operate; (iii) potentially restrict us from pursuing strategic business opportunities; (iv) limit our ability to raise more debt; and (v) increase our exposure to interest rate fluctuation. In addition, we recorded net current liabilities of RMB445.8 million, RMB530.9 million and RMB257.2 million as of December 31, 2018 and 2019 and June 30, 2020, primarily due to our high level of current portion of bank loans of RMB1,979.3 million, RMB1,644.0 million and RMB2,279.2 million, respectively.

The high gearing ratio and net current liabilities position would expose us to liquidity risk which could restrict our ability to make necessary capital expenditure or develop business opportunities, and our business, results of operations and financial condition could be materially and adversely affected.

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## RISK FACTORS

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In addition, we recorded net cash used in operating activities of RMB227.7 million for the six months ended June 30, 2020. Our operating cash outflow was primarily due to (i) a decrease in our sales; (ii) the prolonged settlement of trade receivables by our customers in light of the COVID-19 outbreak; and (iii) increased research and development costs to support our continued R&D efforts. For details, see “Financial Information – Liquidity and Capital Resources – Cash Flows – Operating Activities.” We cannot assure you that we will be able to generate positive cash flows from operating activities in the future. If we continue to record net operating cash outflows in the future, our working capital may be constrained, which may adversely affect our financial condition. Our future liquidity primarily depends on our ability to maintain adequate cash inflows from our operating activities and adequate external financing. If we fail to obtain sufficient funding in a timely manner and on reasonable terms, or at all, our business, financial condition and results of operations may be materially and adversely affected.

***Any significant decrease in our profitability in the future would have a material adverse effect on our ability to recover our deferred tax assets, which could have a material adverse effect on our results of operations.***

We had deferred tax assets of RMB252.8 million as of June 30, 2020. We recognize deferred tax assets to the extent that our management estimates that it is probable that we will generate sufficient taxable profit in the foreseeable future to offset against the deductible losses. Therefore, the recognition of deferred tax assets involves significant judgment and estimates of our management on the timing and level of future taxable profits. When the expectation is different from the original estimate, such differences will impact the recognition of deferred tax assets and taxation charges in the period in which such estimate is changed, and the carrying amount of deferred tax assets may be reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be utilized. Accordingly, if our profitability in the future is significantly lower than our management’s estimates when our deferred tax assets were recognized, our ability to recover such deferred tax assets would be materially and adversely affected, which could have a material adverse effect on our results of operations.

***We have recognized a large amount of goodwill. If our goodwill was determined to be impaired, it could adversely affect our results of operations and financial position.***

As of December 31, 2017, 2018 and 2019 and June 30, 2020, we recorded goodwill of RMB142.5 million, RMB142.5 million, RMB142.5 million and RMB172.8 million, respectively. Goodwill represents the excess of (a) the aggregate of the fair value of consideration transferred, the amount of any non-controlling interest in the acquiree and the fair value of the equity interest in the acquiree previously held by the Group over (b) the net fair value of the acquiree’s identifiable assets and liabilities measured as at the acquisition date.

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## RISK FACTORS

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We do not amortize goodwill, but we conduct impairment reviews at least annually or more frequently if events or changes in circumstances indicate a potential impairment. For the purpose of impairment testing as of December 31, 2017, 2018 and 2019 and June 30, 2020, goodwill has been allocated to the operations of BCY Pharm and our remaining business (the “**pharmaceutical business**”) as individual cash-generating units of our Group. The recoverable amount of each cash-generating unit is determined based on value-in-use calculations. Please see “Financial Information – Critical Accounting Policies and Estimates – Estimated Impairment of Goodwill” for more details. We did not record any impairment charge on goodwill in 2017, 2018 and 2019, and our Directors concluded that there was no impairment indicator of goodwill as of June 30, 2020.

In evaluating the potential for impairment of goodwill, we make assumptions regarding future operating performance, business trends, and market and economic conditions. This analysis further requires us to make assumptions about compounded revenue growth rates, cost and operating expense as a percentage of revenue, useful life of the goodwill, long-term growth rates and pre-tax discount rates. There are inherent uncertainties relating to these factors and our management’s judgment in applying these factors to the assessment of goodwill recoverability. However, we cannot assure you that our assumptions will prove to be correct. We could be required to evaluate the recoverability of goodwill prior to the annual assessment if there are any impairment indicators. Our estimates of the projected cash flows from BCY Pharm and pharmaceutical business may be susceptible to downward revision as a result of factors that have adverse effects, or under circumstances where we fail to sustain the growth we have estimated. If we were required to recognize impairment charges, they could substantially affect our reported earnings in the periods when recognized. In addition, impairment charges could negatively affect our financial ratios, limit our ability to obtain financing and adversely affect our financial position.

***We have intangible assets other than goodwill. If our other intangible assets were determined to require impairment, it could adversely affect our results of operations and financial position.***

As of December 31, 2017, 2018 and 2019 and June 30, 2020, we had intangible assets (other than goodwill) of RMB65.9 million, RMB49.3 million, RMB33.8 million and RMB86.3 million, respectively, which consisted of developed technology, GSP licenses and product trademarks. After initial recognition, we determine whether these intangible assets are impaired at the end of each reporting period if events or changes in circumstance indicate that the carrying amount of these assets exceeds their recoverable amount. As a result, our evaluations in the future on these intangible assets may result in material impairment charges that would have a material adverse impact on our results of operations and potentially the price of our Shares.

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## RISK FACTORS

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***We are subject to liquidity risk in our interests in associates and a joint venture and if our associates and joint venture do not perform as expected or do not generate sufficient revenue in any financial period, our financial condition or results of operations could be materially and adversely affected.***

Our share of losses of associates amounted to RMB1.6 million, RMB8.1 million and RMB4.4 million for the years ended December 31, 2018 and 2019 and the six months ended June 30, 2020, respectively, and our share of losses of a joint venture amounted to RMB0.1 million and RMB40,000 for the year ended December 31, 2019 and the six months ended June 30, 2020, respectively. Our interests in associates and a joint venture may not guarantee a share of profits, and any loss incurred by such associates and joint venture shall be apportioned among our Group and other investors. If our associates and joint venture do not perform as expected or do not generate sufficient revenue in any financial period, our return of interests in our associates and joint venture, and our financial condition or results of operations, could be materially and adversely affected.

In addition, our interests in associates and a joint venture are subject to liquidity risk. Our interests in the associates and joint venture are not as liquid as other investment products as there is no cash flow until dividends are received even if our associates and joint venture reported profits under the equity accounting. Furthermore, our ability to promptly sell one or more of our interests in the associates or joint venture in response to changing economic, financial and investment conditions is limited. The market is affected by various factors, such as general economic conditions, availability of financing, interest rates and supply and demand, many of which are beyond our control. We cannot predict whether we will be able to sell any of our interests in the associates or joint venture for the price or on the terms set by us, or whether any price or other terms offered by a prospective purchaser would be acceptable to us. Therefore, the illiquid nature of our interests in associates or a joint venture may significantly limit our ability to respond to adverse changes in the performance of our associates and joint venture. In addition, if there is no share of results or dividends from our associates or joint venture, we will also be subjected to liquidity risk and our financial condition or results of operations could be adversely affected.

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

We have an internal control system in place to monitor and control potential risk areas relevant to our business operations. In connection with the 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.

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## RISK FACTORS

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

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

***Any technological failure, security breach or other disruptions in our information systems, or those used by our current and future CROs, collaborators or other business partners may adversely affect our business operations.***

Our information systems and those of our current and future CROs, collaboration partners or other business partners may become vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, or accident, and are unaware of any security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption to our development projects and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of data from completed or future pre-clinical studies or clinical trials could result in significant delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be significantly delayed.

***An occurrence of a natural disaster, widespread health epidemic or other outbreaks could have a material adverse effect on our business, financial condition and results of operations.***

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, 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.

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For example, there has been an outbreak of COVID-19. The disease quickly spread within the PRC and globally and materially and adversely affected the global economy. Many hospitals in China allocated significant resources to contain COVID-19, and patients suffering from other diseases generally avoided going to hospitals in order to prevent being infected. As a result, the demand for our products and third-party products we sourced from third-party pharmaceutical companies decreased and some of our distributors reduced their purchases in response to the lowered demand. Meanwhile, pharmacies were not allowed to sell antibiotics, antipyretics and antitussives during the COVID-19 prevention and control period, which had an adverse impact on our sales of relevant products to pharmacy chains. Additionally, our marketing and promotion activities and those of our third-party promoters were postponed or cancelled due to traffic disruption or because the priority of many medical institutions and healthcare professionals became the treatment and containment of COVID-19. Consequently, the timing and the effectiveness of our marketing and promotion efforts as well as those of our third-party promoters were adversely affected. In addition, there were slight delays in conducting certain research and development studies in China, and the continuance of COVID-19 outside of China have also led to delays in research and development process of our overseas collaboration partners. Moreover, the progress of clinical trials was delayed as compared to the original schedule due to delay in patient recruitment, enrollment or follow-ups. The outbreak of COVID-19 could also cause delay of regulatory submissions and required approvals of our product candidates, and could cause us to incur additional costs. If we are not able to effectively develop and commercialize our product candidates as a result of the outbreak of COVID-19, we may not be able to generate revenue from sales of our product candidates as planned.

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

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## RISK FACTORS

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### RISKS RELATING TO THE CONTRACTUAL ARRANGEMENTS

*If the PRC government deems that the Contractual Arrangements do not comply with PRC regulatory restrictions on foreign investment in the relevant industries, or if these regulations or the interpretation of existing regulations change in the future, we could be subject to severe penalties or be forced to relinquish our interests received through the Contractual Arrangements.*

Foreign ownership of certain businesses in PRC is subject to restrictions under current PRC laws and regulations. For example, foreign investors are prohibited from research and development on, or application of, human stem cell and gene diagnosis and treatment technologies.

We were incorporated in Hong Kong as a private company limited by shares, as such, we are classified as a foreign enterprise under PRC laws and regulations, and Shanghai Xianjing, our wholly-owned PRC subsidiary, is considered as a foreign-invested enterprise. We have entered into a series of Contractual Arrangements with each of Shanghai Xianbo, Mr. Ren (who holds 95% equity interest in Shanghai Xianbo) and Mr. Zhu Zhenfei (who holds 5% equity interest in Shanghai Xianbo). Please see “Contractual Arrangements” for a detailed description of the Contractual Arrangements. Through our shareholdings and the Contractual Arrangements, our Company controls the economic benefit of 100% of the equity interest in Shanghai Xianbo.

As advised by our PRC Legal Advisors, save as disclosed in “Contractual Arrangements – Legality of the Contractual Arrangements,” the Contractual Arrangements are legal, valid, enforceable and binding upon the parties thereto under the current laws and regulations. Please see “Contractual Arrangements – Legality of the Contractual Arrangements” for more details. However, our PRC Legal Advisors have also advised us that there are substantial uncertainties regarding the interpretation and application of current or future PRC laws and regulations. In addition, certain PRC court rulings invalidated certain contractual agreements which were considered to be entered into with the intention of circumventing foreign investment restrictions in the PRC in contravention of the PRC Contract Law and the General Principles of the PRC Civil Law. Accordingly, there can be no assurance that the PRC government will ultimately take a view that is consistent with the opinion of our PRC Legal Advisors.

On March 15, 2019, the 2nd meeting of the 13th Standing Committee of the National People’s Congress approved the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (the “**FIL**”) which became effective on January 1, 2020. According to the FIL, the “foreign investment” refers to investment activities carried out directly or indirectly by foreign natural persons, enterprises or other organizations (hereinafter referred to as “**Foreign Investors**”), including the following: (1) Foreign Investors establishing foreign-invested enterprises in China alone or collectively with other investors; (2) Foreign Investors acquiring shares, equities, properties or other similar rights of Chinese domestic enterprises; (3) Foreign Investors investing in new projects in China alone or collectively with other investors; and (4) Foreign Investors investing through other ways prescribed by laws,



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regulations or guidelines of the State Council. However, the interpretation and application of the FIL remain uncertain. In addition, the FIL stipulates that foreign investment includes “Foreign Investors investing in China through many other methods under laws, administrative regulations or provisions prescribed by the State Council.” We cannot assure you that the Contractual Arrangements will not be deemed as a form of foreign investment under laws, regulations or provisions prescribed by the State Council in the future, as a result of which, it will be uncertain whether the Contractual Arrangements will be deemed to be in violation of the foreign investment access requirements and the impact on the Contractual Arrangements. If our ownership structure, Contractual Arrangements and business or that of Shanghai Xianjing or Shanghai Xianbo are found to be in violation of any existing or future PRC laws or regulations, or we fail to obtain or maintain any of the required permits or approvals, we could be subject to several legal liability as follows and without limitation:

- (i) the relevant competent department may order Shanghai Xianjing, Shanghai Xianbo and the shareholders of Shanghai Xianbo to cease the Contractual Arrangements;
- (ii) Shanghai Xianbo may be ordered to dispose the shares or assets thereof or to take any other necessary measures within a prescribed time limit, and to restore the status before the Contractual Arrangements; and
- (iii) the illegal gains (if any) may be confiscated by the relevant competent department.

Any of these actions could cause significant disruption to our business operations and severely damage our reputation, which would result in us failing to receive all or part of the economic benefits from Shanghai Xianbo, which in turn may materially and adversely affect our business, financial condition and results of operations.

Furthermore, new PRC laws, rules and regulations may be introduced to impose additional requirements that may be applicable to our corporate structure and the Contractual Arrangements.

In addition, if any equity interest in Shanghai Xianbo held by its shareholders is held in the court custody in connection with their litigation, arbitration or other judicial or dispute resolution proceedings, we cannot assure you that the equity interest will be disposed of to us in such proceedings in accordance with the Contractual Arrangements. The occurrence of any of these events could adversely affect our business, financial condition and results of operations.

***Our Contractual Arrangements may result in adverse tax consequences to us.***

Under PRC laws and regulations, arrangements and transactions among related parties may be subject to audit or challenge by the PRC tax authorities. We could face material and adverse tax consequences if the PRC tax authorities determine that the Contractual Arrangements were not made on an arm’s length basis and adjust Shanghai Xianbo’s income and expenses for PRC tax purposes by requiring a transfer pricing adjustment. A transfer

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pricing adjustment could materially and adversely affect us by (i) increasing the tax liabilities of Shanghai Xianbo without reducing the tax liability of Shanghai Xianjing, which could further result in late payment fees and other penalties to Shanghai Xianbo for underpaid taxes; or (ii) limiting the ability of Shanghai Xianbo to obtain or maintain preferential tax treatments and other financial incentives.

***The shareholders of Shanghai Xianbo may have potential conflicts of interest with us, which may materially and adversely affect our business and financial condition.***

Our control over Shanghai Xianbo is based upon the Contractual Arrangements with Shanghai Xianbo and its shareholders. These shareholders may potentially have a conflict of interest with us, and they may breach their agreements with us or otherwise act in bad faith, if they believe the Contractual Arrangements would adversely affect their own interests. We cannot assure you that when conflicts of interest arise between us and the shareholders of Shanghai Xianbo, such shareholders will act completely in our interests or that the conflicts of interest will be resolved in our favor. If the shareholders of Shanghai Xianbo do not act completely in our interests or the conflicts of interest between us and them are not resolved in our favor, our business and financial condition may be materially and adversely affected.

Currently, we do not have arrangements to address the potential conflicts of interest faced by one of Shanghai Xianbo's shareholders, namely, Mr. Ren, in his dual capacity as beneficial owner, executive Director and chief executive officer of our Group. We rely on such shareholder to comply with PRC laws and regulations, which protect contracts and provide that directors and executive officers owe a duty of loyalty to us and require them to avoid conflicts of interest and not to take advantage of their positions for personal gains, and the laws of the Hong Kong, which provide that directors have a duty to act in good faith in the interests of us and to avoid conflicts between personal interests and interests of us. However, the legal frameworks of the PRC and the Hong Kong do not provide guidance on resolving conflicts in the event of a conflict with another corporate governance regime.

In addition, the shareholders of Shanghai Xianbo may breach or refuse to renew, or cause Shanghai Xianbo to breach or refuse to renew, the Contractual Arrangements with us. If any such shareholders breaches his agreements with us or otherwise has disputes with us, we may have to initiate arbitration or other legal proceedings, which involve significant uncertainty. Such disputes and proceedings may significantly distract our management's attention, adversely affect our ability to control Shanghai Xianbo and otherwise result in negative publicity and adversely affect the reputation of Shanghai Xianbo. We cannot assure you that the outcome of any such dispute or proceeding will be in our favor.

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*Our Contractual Arrangements may not be as effective in providing operational control as direct ownership. Shanghai Xianbo and its shareholders may fail to perform their obligations under our Contractual Arrangements.*

We have no equity ownership interests in Shanghai Xianbo and rely on the Contractual Arrangements with Shanghai Xianbo and its shareholders to control the entire equity ownership interests in Shanghai Xianbo. Please see “History, Reorganization and Corporate Structure – Reorganization – Onshore Reorganization – Contractual Arrangements.” Although we have been advised by our PRC Legal Advisors that our Contractual Arrangements constitute valid and binding obligations enforceable against each party of such agreements in accordance with their terms, these Contractual Arrangements may not be as effective in providing us with control over Shanghai Xianbo as direct ownership. Direct ownership would allow us, for example, to directly or indirectly exercise our rights as a shareholder to effect changes in the board of directors of Shanghai Xianbo, which, in turn, could effect changes, subject to any applicable fiduciary obligations, at the management level. If Shanghai Xianbo or any of its shareholders fails to perform its respective obligations under the Contractual Arrangements, we may incur substantial costs and expend substantial resources to enforce our rights. All of these Contractual Arrangements are governed by and interpreted in accordance with PRC laws, and disputes arising from these Contractual Arrangements will be resolved through arbitration in China. However, the legal system in China is not as developed as in other jurisdictions, such as the United States. There are very few precedents and little official guidance as to how contractual arrangements in the context of a variable interest entity should be interpreted or enforced under PRC law. There remain significant uncertainties regarding the outcome of arbitration or litigation. These uncertainties could limit our ability to enforce these Contractual Arrangements. The Contractual Arrangements contain provisions to the effect that the arbitral body may award remedies over the shares and/or assets of Shanghai Xianbo, injunctive relief and/or winding up of it. These agreements also contain provisions to the effect that courts of competent jurisdictions are empowered to grant interim remedies in support of the arbitration pending the formation of an arbitral tribunal. However, under PRC laws, these terms may not be enforceable. Under PRC laws, an arbitral body does not have the power to grant injunctive relief or to issue a provisional or final liquidation order. In addition, interim remedies or enforcement order granted by overseas courts such as Hong Kong may not be recognizable or enforceable in the PRC. In the event we are unable to enforce these Contractual Arrangements or we experience significant delays or other obstacles in the process of enforcing these Contractual Arrangements, we may not be able to exert effective control over Shanghai Xianbo or obtain the full economic benefits of the same. Our ability to conduct our business may be negatively affected.

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***We may lose control over Shanghai Xianbo and may not enjoy its full economic benefits if Shanghai Xianbo declares bankruptcy or become subject to a dissolution or liquidation proceeding.***

Our Contractual Arrangements contain terms that specifically provide that Shanghai Xianbo may not be voluntarily liquidated without the written consent of Shanghai Xianjing. However, if the shareholders of Shanghai Xianbo breach this obligation and voluntarily liquidate Shanghai Xianbo or if Shanghai Xianbo declares bankruptcy, all or part of its assets may become subject to liens or rights of third-party creditors and we may be unable to continue to control Shanghai Xianbo and may not enjoy the full economic benefits of the same, which could adversely affect our business, financial condition and results of operations.

If the shareholders of Shanghai Xianbo were to attempt to voluntarily liquidate Shanghai Xianbo without obtaining our prior consent, we could effectively prevent such unauthorized voluntary liquidation by exercising our right to request such shareholders to transfer all of their equity ownership interests in Shanghai Xianbo to us or to an entity designated by us in accordance with the exclusive option agreement between Shanghai Xianbo, its shareholders and us. In addition, under the Contractual Arrangements, the shareholders of Shanghai Xianbo do not have the right to issue dividends to themselves or otherwise distribute the retained earnings or other assets of Shanghai Xianbo without our prior consent. In the event that the shareholders of Shanghai Xianbo initiate a voluntary liquidation proceeding without our authorization or attempt to distribute the retained earnings or assets of Shanghai Xianbo without our prior consent, we may need to resort to legal proceedings to enforce the terms of the Contractual Arrangements. Any such legal proceeding may be costly and may divert our management's time and attention away from the operation of our business, and the outcome of such legal proceeding will be uncertain.

***If we exercise the option to acquire equity ownership of Shanghai Xianbo, the ownership transfer may subject us to certain limitations and substantial costs.***

Pursuant to the Contractual Arrangements, Shanghai Xianjing or its designated person(s) has the exclusive right to purchase all or any part of the equity interest in Shanghai Xianbo from its shareholders free of charge or at a nominal consideration, or if the aforementioned consideration is not permitted under then applicable PRC laws, at the minimum consideration permitted under such laws.

The equity transfer may be subject to approvals from and filings with the MOFCOM or its local counterparts. In addition, the equity transfer price may be subject to review and tax adjustment by the relevant tax authority. The shareholders of Shanghai Xianbo will pay the remaining amount to Shanghai Xianjing under the Contractual Arrangements. The amount to be received by Shanghai Xianjing may also be subject to enterprise income tax. Such tax amounts could be substantial and our financial condition may be adversely affected as a result.

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## RISK FACTORS

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### RISKS RELATING TO DOING BUSINESS IN CHINA

*China's economic, political and social conditions and government policies, as well as the global economy, may continue to affect our business.*

Substantially all of our businesses, assets, operations and revenues are located in or derived from our operations in the PRC and, as a result, our business, financial condition and results of operations are subject, to a significant degree, to the economic, political, social and regulatory environment in the PRC.

The PRC government regulates the economy and the industries by imposing industrial policies and regulating the PRC's macro economy through fiscal and monetary policies. Certain industrial policies are more favorable to traditional medicines, State-owned pharmaceutical companies or emerging biotechnology companies which compete against us, which may have an adverse effect on us. Our financial condition and results of operations 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 businesses.

The PRC economy has undergone a transition from a planned economy to a market-oriented economy. The PRC government has, in recent years, taken various actions to introduce market forces for economic reform, to reduce state ownership of productive assets and to promote the establishment of sound corporate governance in business entities. However, a substantial portion of productive assets in the PRC are still owned by the PRC government. In addition, the PRC government continues to play a significant role in regulating the economy and the industries by issuing industrial policies. The PRC government still retains significant control over the PRC's economic growth through the allocation of resources, monetary policies and preferential treatments to particular industries or enterprises.

Our performance has been and will continue to be affected by China's economy, which in turn is influenced by the global economy. The uncertainties relating to the global economy as well as the political environment in various regions of the world will continue to impact China's economic growth. While China's economy has experienced significant growth in the past few decades, growth has been uneven across different regions and economic sectors and there is no assurance that such growth can be sustained. The global economic slowdown and the turmoil in the global financial markets that began in the second half of 2008, continued weakness in the U.S. economy and the sovereign debt crisis in Europe have collectively added downward pressure to economic growth in China. The growth rate of China's real GDP has decreased from 7.3% in 2014 to 6.1% in 2019.

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## RISK FACTORS

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We are unable to predict all the risks and uncertainties that we face as a result of current economic, political, social, and regulatory developments and many of these risks are beyond our control. All such factors may materially and adversely affect our business and operations as well as our financial performance.

***The M&A Rules and certain other PRC regulations establish complex procedures for some acquisitions of Chinese companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.***

The M&A Rules, adopted by six PRC regulatory agencies in 2006 and amended in 2009, and some other regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex, including requirements in some instances that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise. Moreover, the Anti-Monopoly Law (《反壟斷法》) requires that the MOFCOM shall be notified in advance of any concentration of undertaking if certain thresholds are triggered. In addition, the Rules 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》) issued 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 rules prohibit 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.

***Our operations are subject to the uncertainties and particularities associated with the legal system in China, which could adversely affect our business, or 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 laws and regulations. The PRC legal system is based on written statutes and their interpretation by the Supreme People’s Court of the PRC and may not be as comprehensive or developed as that of other jurisdictions. Prior court decisions may be cited for reference but have limited precedential value. Accordingly, the outcome of dispute resolutions may not be consistent or predictable.

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Although efforts have been made by the PRC government to enhance protection of foreign investment in the PRC, the PRC has not yet developed a fully integrated legal system. Newly enacted laws and regulations may not sufficiently cover all aspects of economic activities in the PRC and there is much uncertainty in their application, interpretation and enforcement. Furthermore, the PRC legal system is partly based on government policies and administrative rules that may take effect retrospectively. As a result, we may not be aware of our violations of certain policies or rules in a timely manner.

The legal protection available to us under the PRC laws and regulations may be limited. Any litigation or regulatory enforcement action in the PRC may be protracted, which may result in the diversion of our resources and management attention. In addition, the outcome of dispute resolutions may not be consistent or predictable and it may be difficult to enforce judgments and arbitration awards in the PRC.

These uncertainties relating to the interpretation, implementation and enforcement of the PRC laws and regulations and a system of jurisprudence that gives only limited precedential value to prior court decisions can affect the legal remedies and protections available to you and may adversely affect the value of your investment.

Meanwhile, laws, regulations or enforcement policies in China, including those regulating healthcare and the pharmaceutical industry, are evolving and subject to frequent changes. 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.

*Anti-monopoly claims or regulatory actions against us may expose us to penalties, business constraints and reputation damages.*

The PRC anti-monopoly enforcement agencies have in recent years strengthened enforcement under the PRC Anti-monopoly Law. In March 2018, the SAMR was formed as a new governmental agency to take over, among other things, the anti-monopoly enforcement functions from the relevant departments under the MOFCOM, the NDRC and the SAIC, respectively. Since its inception, the SAMR has continued to strengthen its anti-monopoly enforcement, including the issuance of the “Notice on Anti-monopoly Enforcement Authorization” (《國家市場監督管理總局關於反壟斷執法授權的通知》) on December 28, 2018, which grants authorizations to the branches of SAMR at the provincial level for anti-monopoly enforcement within their respective jurisdictions. On June 26, 2019, the SAMR promulgated the “Interim Provisions on Prohibiting Monopoly Agreement” (《禁止壟斷協議暫行規定》) and the “Interim Provisions on Prohibiting Abuse of Dominant Market Positions” (《禁止濫用市場支配地位行為暫行規定》) (collectively, the “**Interim Provisions**”), which

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became effective on September 1, 2019. Pursuant to the PRC Anti-monopoly Law and the Interim Provisions, companies are prohibited from reaching monopoly agreements on price of products with their counterparties, including directly or indirectly fixing resale price of products or limiting bottom resale price of products; companies are also prohibited from conducting abusive behaviors leveraging their market dominance, including selling products at unfairly high prices and directly or indirectly refusing to transact with specific counterparties without justification. The relevant anti-monopoly laws also provide a private right of action for competitors, business partners or customers who suffered losses caused by monopolistic behaviors to bring anti-monopoly claims. In recent years, an increasing number of companies have been exercising their right to seek relief under the PRC Anti-monopoly Law.

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

Although we believe that our business practices are conducted based on commercially reasonable considerations and justifications and do not violate the PRC Anti-monopoly Law or the Interim Provisions, there can be no assurance that other companies, including our competitors, business partners and customers, will submit complaints to regulators or initiate private litigation that targets our prior and current business practices, nor can we assure you that regulators will not initiate anti-monopoly investigations into specific business practices we have adopted. We are currently involved in an investigation initiated by the SAMR in respect of our alleged violation of the PRC Anti-monopoly Law. The investigation is still pending and SAMR has not reached any decision. Please see “Business – Legal Proceedings and Compliance – Legal Proceedings – Anti-monopoly Investigation” for more details. We cannot assure you that we will not be subject to any further or other investigations in the future. Any existing or future anti-monopoly lawsuit, regulatory investigations or administrative proceedings initiated against us, regardless of their merits, could materially and adversely harm our business and reputation. If we are perceived to violate anti-monopoly laws, regulations or policies in the PRC, we will be exposed to penalties, confiscation of illegal gains and cease of illegal business practices, which could materially and adversely affect our business, results of operations and financial condition.



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

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

Pursuant to the EIT Law and its implementation rules, if an enterprise incorporated outside the PRC has its “de facto management bodies” within China, such enterprise would generally be deemed a “PRC resident enterprise” for tax purposes and be subject to an EIT rate of 25% on its global income. “De facto management bodies” is defined as the body that has actual overall management and control over the business, personnel, accounts and properties of an enterprise. In April 2009, July 2011 and January 2014, the STA issued several circulars to clarify certain criteria for the determination of the “de facto management bodies” in respect of enterprises that are established offshore by PRC enterprises, which could be applied in determining the tax resident status of non-PRC enterprises.

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 regarded as PRC resident enterprise by the PRC tax authorities, we would have to pay PRC EIT at a rate of 25% for our entire global income, which may materially and adversely affect our profits and hence our retained profit available for distribution to our Shareholders.

Furthermore, under the EIT Law and its implementation rules, unless otherwise reduced or exempted by the tax treaties or similar arrangements, PRC withholding tax at a rate of 10% is normally applicable to income from a PRC source paid to “non-resident enterprises,” which do not have an establishment or place of business in China, or which have such establishment or place of business but whose relevant income is not effectively connected with the establishment or place of business. According to the “Treaty on the Avoidance of Double Taxation and Tax Evasion between Mainland China and Hong Kong” (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) which was entered into on August 21, 2006, taxes on dividends paid by a PRC resident enterprise to a Hong Kong resident enterprise, or vice versa, can be levied by competent authorities in the PRC or in Hong Kong, provided that the withholding tax shall not exceed 5% of the total dividends if the payee beneficially owns 25% or more interest in the payor. Consequently, dividends payable to our Company by those PRC resident enterprises in which it beneficially owns 25% or more interest may be subject to a reduced withholding tax rate of 5%. While, if we are treated as a PRC resident enterprise, dividends payable to our investors that are “non-resident enterprises” may be treated as income derived from sources within China. Any gain realized on the transfer of shares by investors that are “non-resident enterprises” is generally subject to a 10% PRC income tax if such gain is regarded as income derived from sources within China. In addition, under PRC Individual Income Tax Law and its implementation rules, dividends from sources

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within China paid to foreign individual investors who are not PRC residents are generally subject to a PRC withholding tax at a rate of 20% and gains from PRC sources realized by such investors on the transfer of shares are generally subject to PRC income tax at a rate of 20% for individuals.

If we are treated as a PRC resident enterprise, dividends we pay with respect to our Shares, or the gain realized from the transfer of our Shares, may be treated as income derived from sources within China and as a result be subject to the PRC income taxes described above. If PRC income tax is imposed on gains realized through the transfer of our Shares or on dividends paid to our non-resident investors, the value of your investment in our Shares may be materially and adversely affected.

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

On February 3, 2015, the STA issued the “Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises” (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (“**Circular 7**”), which abolished certain provisions in the “Notice on Strengthening the Administration of Enterprise Income Tax on Non-Resident Enterprises” (《關於加強非居民企業股權轉讓企業所得稅管理的通知》) (“**Circular 698**”), which was previously issued by the STA on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 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 (“**PRC Taxable Assets**”).

For example, Circular 7 specifies that the PRC tax authorities are entitled to reclassify the nature of an indirect transfer of PRC Taxable Assets according to Article 47 of the EIT Law, when a non-resident enterprise transfers 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 PRC Taxable Assets, if such transfer is deemed to have been conducted for the purposes of avoiding PRC enterprise income taxes and without any other reasonable commercial purpose.

Except as provided in Article 5 and Article 6 of Circular 7, transfers of Chinese taxable property under the following circumstances shall be automatically deemed as having no reasonable commercial purpose, and are subject to PRC enterprise income tax: (i) more than 75% of the equity value of the overseas enterprise is directly or indirectly from Chinese taxable properties; (ii) more than 90% of the total assets (cash excluded) of the overseas enterprise are directly or indirectly composed of investment in China at any time during the year prior to the indirect transfer of Chinese taxable property, or more than 90% of the income of the overseas enterprise is directly or indirectly from China during the year prior to the indirect transfer of Chinese taxable property; (iii) the overseas enterprise and its subsidiaries directly or indirectly

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hold Chinese taxable property and have registered in the host countries (regions) in order to meet the local legal requirements in relation to organization forms, yet prove to be lack of economic substance due to their inadequate ability to perform their intended functions and withstand risks as their alleged organization forms suggest; or (iv) the income tax from the indirect transfer of Chinese taxable property payable abroad is lower than the income tax in China that may be imposed on the direct transfer of such PRC Taxable Assets.

Although Circular 7 contains certain exemptions (including, (i) where a non-resident enterprise derives income from the indirect transfer of 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 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 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 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.

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

***The PRC government’s control of foreign currency conversion and restrictions on the remittance of RMB out of the PRC may limit our foreign exchange transactions and our ability to pay dividends and meet other obligations, and affect the value of your investment.***

The PRC government imposes controls on the convertibility of the RMB into foreign currencies and, in certain cases, the remittance of currency out of China. We receive substantially all of our revenue in RMB. We may convert a portion of our revenue into other currencies to meet our foreign currency obligations, such as payments of dividends declared in

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respect of our Shares, if any. Shortage in the availability of foreign currency may restrict the ability of our PRC subsidiaries to remit sufficient foreign currency out of China, or otherwise satisfy their foreign currency denominated obligations.

Under existing PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. However, approval from or registration with appropriate governmental authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies.

In light of the flood of capital outflows of China in 2016 due to the weakening of the RMB, the PRC government has imposed more restrictive foreign exchange policies and stepped up scrutiny of major outbound capital movements. More restrictions and substantial vetting process are put in place by SAFE to regulate cross-border transactions falling under the capital account. The PRC government may at its discretion further restrict access to foreign currencies in the future for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders.

***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. In addition, certain loan agreements signed by our PRC subsidiaries 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.

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***Inflation in the PRC could negatively affect our profitability and growth.***

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 severely hamper our growth.

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

The value of the RMB against the Hong Kong dollars, the U.S. dollars, Euro and other currencies fluctuates, is subject to changes resulting from the PRC government's policies and depends to a large extent on domestic and international economic and political developments as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between the RMB and the Hong Kong dollars, the U.S. dollars, Euro or other currencies in the future. In addition, the PBOC regularly intervenes in the foreign exchange market to limit fluctuations in RMB exchange rates and achieve policy goals.

In the Track Record Period, substantially all of our revenues and expenditures were denominated in Renminbi, and substantially all of our financial assets are also denominated in Renminbi. Therefore, we mainly rely on dividends and other fees paid to us by our PRC subsidiaries. Any significant change in the exchange rates of the Hong Kong dollars 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.

Certain of our bank loans are denominated in foreign currencies such as Euro. Fluctuations in exchange rates of these foreign currencies against Renminbi may have an adverse impact on our results of operations.

The proceeds from the Global Offering will be received in Hong Kong dollars. As a result, any appreciation of the RMB against the Hong Kong dollars may result in the decrease in the value of our proceeds from the Global Offering. Conversely, any depreciation of the RMB may adversely affect the value of, and any dividends payable on, the Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

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*PRC regulation of loans to and direct investments in PRC entities by offshore holding companies may delay or prevent us from using the proceeds of the Global Offering to make loans or additional capital contributions to our PRC subsidiaries, which could materially and adversely affect our liquidity and our ability to fund and expand our business.*

Any funds we transfer to our PRC subsidiaries, either as a shareholder loan or as an increase in registered capital, are subject to approval by or registration with relevant governmental authorities in China.

According to the relevant PRC regulations on foreign-invested enterprises in China, capital contributions by us to our PRC subsidiaries are subject to the requirement of making necessary filings in the enterprise registration system and registration with the relevant governmental authorities in China. In addition, any foreign loan provided by us to our PRC subsidiaries is required to be registered with SAFE, or its local counterparts. We may not be able to complete such recording or registrations on a timely basis, if at all, with respect to future capital contributions or foreign loans by us directly to our PRC subsidiaries. If we fail to complete such recording or registration, our ability to use the proceeds of the Global Offering and to capitalize our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

On March 30, 2015, the SAFE promulgated the “Circular on Reforming the Management Approach Regarding the Foreign Exchange Capital Settlement 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》) (“**SAFE Circular 19**”), which took effect on June 1, 2015 and was amended on December 30, 2019. SAFE Circular 19 launched a nationwide reform of the administration of the settlement of the foreign exchange capitals of foreign-invested enterprises and allows foreign-invested enterprises to settle their foreign exchange capital at their discretion, but continues to prohibit foreign-invested enterprises from using RMB funds converted from their foreign exchange capital for expenditures beyond their business scopes. On June 9, 2016, the SAFE promulgated the “Circular on Reforming and Standardizing the Administrative Provisions on Capital Account Foreign Exchange” (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (“**SAFE Circular 16**”). SAFE Circular 19 and SAFE Circular 16 continue to prohibit foreign-invested enterprises from, among other things, using RMB funds converted from their foreign exchange capital for expenditure beyond their business scope, investment and financing (except for securities investment or non-guaranteed bank products), providing loans to non-affiliated enterprises or constructing or purchasing real estate not for self-use. SAFE Circular 19 and SAFE Circular 16 may significantly limit our ability to transfer to and use in China the proceeds from the Global Offering, which may materially and adversely affect our business, financial condition and results of operations.

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On September 14, 2015, the NDRC issued the “Circular on Promoting the Reform of the Administrative System on the Filings and Registrations of Foreign Debt Issuance by Enterprises” (《國家發展改革委關於推進企業發行外債備案登記制管理改革的通知》(發改外資[2015]2044號)) (the “**Circular 2044**”), which requires domestic enterprises and their overseas subsidiaries or branches to file and register with the NDRC prior to issuance of any foreign debt that matures in more than one year, and to notify the NDRC of the particulars of such issuance, along with an explanation to the significant discrepancy between the registration record and the actual issuance, if any, within 10 business days upon completion of issuance. For enterprises that willfully misstate the issuance scale of foreign debts, the NDRC will record their bad credit in the National Credit Information Platform. Further in February 2020, the NDRC issued the “Guidance on the Filings and Registrations of Foreign Debt Issuance by Enterprises” (《企業發行外債備案登記辦事指南》) (the “**Guidance**”), which sets out detailed guidelines and procedures during the relevant filings and registrations.

However, the interpretation and implementation of the Circular 2044 and the Guidance are subject to broad discretion of the NDRC, therefore involving substantial uncertainty. The NDRC may also, from time to time, revise the Circular 2044 or the Guidance, or adjust their scopes of application. If we fail to file or register any foreign debt issuance with the NDRC in accordance with the Circular 2044 and the Guidance, we may not be able to use the proceeds of such foreign debt issuance to capitalize our PRC operations due to incapable of completing foreign exchange capital settlement. In addition, if the NDRC records our bad credit in the National Credit Information Platform, our ability to access future fundings as well as to make investments could be materially and adversely affected.

*We may be subject to penalties, including restrictions on our ability to inject capital into our PRC subsidiaries and our PRC subsidiaries’ ability to distribute profits to us, if our PRC resident Shareholders or beneficial owners fail to comply with relevant PRC foreign exchange regulations.*

The SAFE has promulgated several regulations that require PRC residents and PRC corporate entities to register with and obtain approval from local counterparts of the SAFE in connection with their direct or indirect offshore investment activities.

The SAFE promulgated the “Circular on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Financing and Round-trip Investment through Offshore Special Purpose Vehicles” (《國家外匯管理局關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) (“**SAFE Circular 75**”) on October 21, 2005, which requires a PRC resident (whether a natural person or a legal person) to register with the local counterpart of the SAFE before it establishes or controls an offshore SPV, with assets or equity interests in a PRC company, for the purpose of overseas equity financing. In July 2014, the SAFE promulgated the “Circular on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Overseas Investment and Financing and Round-trip Investment through Special Purpose Vehicles” (《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》) (“**SAFE Circular 37**”), which replaced the SAFE Circular 75. SAFE Circular 37 requires PRC residents or entities to register with

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SAFE or its local counterparts in connection with their establishment or control of an offshore entity, for the purpose of overseas investment or financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” Further, on February 13, 2015, SAFE promulgated the “Notice on Further Simplifying and Improving the Foreign Exchange Administration Policies for Direct Investment” (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) (“**SAFE Circular 13**”), which came into effect on June 1, 2015 and was partially abolished on December 30, 2019. SAFE Circular 13 cancels two administrative approval items: foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment. Instead, banks shall directly examine and handle foreign exchange registration under both domestic direct investment and overseas direct investment, and SAFE and its local counterparts shall indirectly regulate the foreign exchange registration of direct investment through banks. These regulations apply to our Shareholders who are PRC residents and may apply to any offshore acquisitions that we make in the future.

Under these foreign exchange regulations, PRC residents who make, or have previously made, prior to the implementation of these foreign exchange regulations, direct or indirect investments in offshore companies are required to register those investments. In addition, any PRC resident who is a direct or indirect shareholder of an offshore company is required to update the previously filed registration with the local counterpart of the SAFE, with respect to that offshore company, to reflect any material change involving its round-trip investment, capital variation, such as an increase or decrease in capital, transfer or swap of shares, merger or division.

If any PRC shareholder fails to make the required registration or update the previously filed registration, the PRC subsidiary of that offshore parent company may be restricted from distributing their profits and the proceeds from any reduction in capital, share transfer or liquidation to their offshore parent company, and the offshore parent company may also be restricted from injecting additional capital into its PRC subsidiary. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC laws for evasion of applicable foreign exchange restrictions, including but not limited to (i) the requirement by the SAFE to return the foreign exchange remitted overseas or into the PRC within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas or into the PRC and deemed to have been evasive or illegal 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 or illegal.

We have requested PRC residents that to our knowledge hold direct or indirect interest in our Company to make the necessary applications, filings and amendments as required by applicable foreign exchange regulations. The relevant individuals have duly completed the initial foreign exchange registrations in relation to their offshore investments as PRC residents in accordance with SAFE Circular 75, SAFE Circular 37 and SAFE Circular 13. However, there can be no assurance that the subsequent amendment of registration, when required, can be successfully completed in a timely manner. Failure by any Shareholders to comply with



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SAFE Circular 37 or other related regulations could subject us to fines or legal sanctions, restrict our investment activities in the PRC and 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.

As there is uncertainty concerning the reconciliation of these foreign exchange regulations with other approval requirements, it is unclear how these regulations, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant governmental authorities. We cannot predict how these regulations will affect our business operations or future strategy. For example, we may be subject to a more stringent review and approval process with respect to our foreign exchange activities, such as remittance of dividends and foreign-currency-denominated borrowings, which may materially and adversely affect our results of operations and financial condition. In addition, if we decide to acquire a PRC domestic company, we cannot assure you that we or the owners of such company, as the case may be, will be able to obtain the necessary approvals or complete the necessary filings and registrations required by the foreign exchange regulations. This may restrict our ability to implement our acquisition strategy and could materially and adversely affect our business and prospects.

*Failure to comply with PRC regulations regarding the registration requirements for employee share incentive plans may subject the PRC plan participants or us 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 Share 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 “**Share Incentive Rules**”), which replaced the earlier rules promulgated by the SAFE in March 2007. Under the Share Incentive Rules, PRC residents who participate in share incentive plans in an overseas publicly listed company are required, through a PRC agent or PRC subsidiary of such 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 share options, the purchase and sale of corresponding shares or interests and fund transfers. In addition, the PRC agent is required to amend the SAFE registration with respect to the share incentive plan if there is any material change to the share incentive plan, the PRC agent or the overseas entrusted institution or other material changes.

We and our PRC resident employees who have been granted share options will be subject to the Share Incentive Rules upon completion of the Global Offering. Failure of the PRC resident holders of our share options to complete their SAFE registrations may subject these PRC residents or our PRC subsidiaries to regulatory measures and legal sanctions and may materially adversely affect our business.

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## RISK FACTORS

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*You may experience difficulties in effecting service of legal process and seeking recognition and enforcement of foreign judgments in China.*

Substantially all of our assets are located in China and substantially all of our current operations are conducted in China as well. In addition, a majority of our current Directors and senior management members are nationals and residents of China and most of the assets of these persons are located in China. It may not be possible for investors to effect service of process upon us or those persons in the PRC for disputes brought in courts outside the PRC. The PRC has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

On July 14, 2006, Hong Kong and 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 (《最高人民法院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 “**Arrangement**”), pursuant to which a party with an enforceable final court judgment rendered by any designated PRC court or any designated Hong Kong court requiring payment of money in a civil and commercial case according to a written choice of court agreement, may apply for recognition and enforcement of the judgment in the relevant PRC court or Hong Kong court. A written choice of court agreement is defined as any agreement in writing entered into between parties after the effective date of the 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 may not be possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in the dispute did not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against us, certain of our assets, our Directors and senior management members in the PRC in order to seek recognition and enforcement of foreign judgments in the PRC. On January 18, 2019, Hong Kong and 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 (《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 “**New Arrangement**”), which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong and the PRC. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court of the PRC and the completion of the relevant legislative procedures in Hong Kong. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective, it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

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## RISK FACTORS

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### RISKS RELATING TO THE GLOBAL OFFERING

*No public market currently exists for our Shares; the market price of 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 Global Coordinators (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 various 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;
- developments in China healthcare and pharmaceutical 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.

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## RISK FACTORS

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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 Offering will experience an immediate dilution in pro forma consolidated net tangible asset value to HK\$1.91 per Share, based on the mid-point of the Offer Price range of HK\$12.90. There can be no assurance that if we were to immediately liquidate after the Global Offering, any assets will be distributed to Shareholders after the creditors' claims. 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.

***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 Controlling Shareholders have significant influence over our Company and their interests may not be aligned with the interest of our other Shareholders.***

Immediately following the Global Offering, our Controlling Shareholders will hold in aggregate approximately 78.13% of our Shares, assuming the Over-allotment Option is not exercised. Our Controlling Shareholders will, through their 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 Controlling Shareholders may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling Shareholders, we could be prevented from entering into transactions that could be

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## RISK FACTORS

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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.

***We have significant discretion as to how we will use the net proceeds of the Global Offering, and you may not necessarily agree with how we use them.***

Our management may utilize the net proceeds from the Global Offering in ways you may not agree with or that do not yield a favorable return to our Shareholders. We plan to use the net proceeds from the Global Offering, including but not limited to: the continued research and development of our selected product candidates in our strategically focused therapeutic areas, the reinforcement of our sales and marketing capabilities, our investment in companies in the pharmaceutical or biotechnology sector when appropriate opportunities arise and working capital and other general corporate purposes. Please see “Future Plans and Use of Proceeds – Use of Proceeds” for more details. However, our management will have discretion as to the actual application of our net proceeds. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net proceeds from the Global Offering.

***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 several 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.

***We may not pay any dividends on the Shares.***

We cannot guarantee when, if, or in what form, dividends will be paid on the Shares following the Global Offering. A declaration of dividends must be proposed by our Board and will be based on, and limited by, various factors, including our business and financial performance, capital and regulatory requirements and general business conditions. Furthermore, we may not have sufficient profits to make dividend distributions to Shareholders in the future, even if our financial statements prepared under HKFRS indicate that our operations have been profitable. Please see “Financial Information – Dividends” for more details on our dividend policy.

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## RISK FACTORS

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***Facts, forecasts and statistics in this prospectus relating to the PRC economy and healthcare and pharmaceutical industry may not be fully reliable.***

Facts, forecasts and statistics in this prospectus relating to the PRC, the PRC economy and healthcare and pharmaceutical industry in China are obtained from various sources including official government publications that we believe are reliable. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Joint Global Coordinators nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and market practice and other problems, the statistics in this prospectus relating to the PRC economy and the healthcare and pharmaceutical industry in China may be inaccurate or may not be comparable to statistics produced for other economies and should not be unduly relied upon. As such, no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources is made. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon. Further, there can be no assurance that they are stated or compiled on the same basis or with the same degree of accuracy, as may be the case in other countries.

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

The trading market for our Shares will be influenced by research or reports that industry or securities analysts publish about us or our business. If one or more analysts who cover us downgrade our Shares or publishes negative opinions about us, the market price for our Shares would likely decline regardless of the accuracy of the information. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the market price or trading volume of our Shares to decline.

***You should only rely on the information included in this prospectus to make your investment decision, and we strongly caution you not to rely on any information contained in press articles or other media coverage relating to us, our Shares or the Global Offering.***

There had 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 media coverage regarding us and the Global Offering. We have not authorized the disclosure of any information concerning the Global Offering in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this prospectus, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their decisions on the basis of the information contained in this prospectus only and should not rely on any other information.