

## BUSINESS

### OVERVIEW

We are rapidly transitioning to an innovation and R&D-driven pharmaceutical company, leveraging our leading manufacturing and commercial capabilities to achieve our mission of “providing today’s patients with medicines of the future” (讓患者早日用上更有效藥物). We have been continuously recognized as one of the “Top 10 Innovative Pharmaceutical Enterprise in China (中國創新力醫藥企業十強)” and “Top 100 Pharmaceutical Manufacturing Enterprises of China (中國製藥工業百強)”, with category I innovative pharmaceuticals contributing 21.4%, 25.5% and 32.9% of our total revenue for the years ended December 31, 2017, 2018 and 2019, respectively. We have a diversified and leading innovative product portfolio in our strategically focused therapeutic areas, including, (i) oncology (including cell therapy), (ii) central nervous system diseases and (iii) autoimmune diseases. According to Frost & Sullivan, together, these therapeutic areas accounted for 24.7% of the total PRC pharmaceutical market in terms of sales revenue of pharmaceuticals in 2019 and grew faster than the overall PRC pharmaceutical market from 2015 to 2019, a trend which is expected to continue overall in the near future, according to Frost & Sullivan.

Our diversified innovative product portfolio centers around a number of innovative pharmaceuticals with leading positions in their respective therapeutic segments. Our category I innovative pharmaceuticals, namely, Endostar (recombinant human endostatin injection, the first proprietary anti-angiogenic targeted drug in China and the only endostatin approved for sale in China and worldwide<sup>1</sup>) and Iremod (iguratimod tablets, a small molecule DMARD, the first iguratimod pharmaceutical product approved for sale in the world<sup>1</sup>), contributed 21.4%, 25.5% and 32.9% of our total revenue for the years ended December 31, 2017, 2018 and 2019, respectively. Recombinant human endostatin and iguratimod have been included in the NRDL since 2017 and we believe they have tremendous commercial value. In particular, recombinant human endostatin is recommended as a first-line treatment for advanced NSCLC patients by a number of oncology clinical practice guidelines issued by NHC, Chinese Medical Association (中華醫學會) and CSCO; while iguratimod has been recommended as the primary therapy drug for the treatment of active rheumatoid arthritis by a number of clinical practice guidelines and pathways issued by the NHC, Chinese Medical Association, Asia Pacific League of Associations for Rheumatology and the Ministry of Health, Labor and Welfare of Japan. We expect to be able to launch in 2020 and 2021 the sales and/or promotion of innovative near-commercial products including edaravone and dexborneol concentrated solution for injection (an edaravone compound with significantly higher efficacy than edaravone monotherapy in patients with ischemic stroke) and KN035 (Envafolimab) (a subcutaneously injectable PD-L1 inhibitor), both of which are category I innovative pharmaceuticals, as well as Orencia® (abatacept injection) (a CTLA4-Fc fusion protein for the treatment of moderate to severe rheumatoid arthritis), which is an imported innovative pharmaceutical. We believe that our commercial and near-commercial innovative products have significant market potential and will continue to drive our future growth.

We have been continuously increasing our investment in R&D over the years. As of December 31, 2019, our R&D department consisted of 699 full-time employees, 292 of whom held master’s degrees and 113 held Ph.D. degrees. We have established three R&D centers in

<sup>1</sup> According to Frost & Sullivan.

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## BUSINESS

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Nanjing (the Jiangsu Province), Shanghai and Boston (the United States), respectively. With the approval of the Ministry of Science and Technology, we have also established a national key laboratory of translational medicine and innovative pharmaceuticals (轉化醫學與創新藥物國家重點實驗室). For the years ended December 31, 2017, 2018 and 2019, our research and development costs accounted for 5.5%, 9.9% and 14.2%, respectively, of our total revenue for the same periods. Capitalizing on our proven track record of in-house development together with a global vision, we have established a distinct open innovation model. Our dedicated business development team stays keen on market developments and actively pursues potential collaboration opportunities. We have successfully established collaboration relationships with leading domestic and international pharmaceutical companies and biotechnology companies, securing exclusive development and commercialization rights in China. Our vigorous in-house R&D efforts and extensive R&D collaborations have translated into a robust pipeline of product candidates. As of the Latest Practicable Date, we had nearly 50 innovative product candidates in different stages of development, including small molecule pharmaceuticals, large molecule pharmaceuticals and CAR T-cell therapies, among which over 10 product candidates were at clinical stage, had submitted NDA or had obtained NDA pending market launch. We plan to collaborate with Jiangsu Alphamab and 3D Medicines Beijing to develop a number of combination therapies with KN035 for the treatment of solid tumors, in order to further enhance the competitiveness of KN035.

We are a vertically integrated pharmaceutical company with established manufacturing and commercial capabilities. We maintain an effective and nationwide sales and distribution network supported by over 2,600 sales and marketing personnel spanning 31 provinces, municipalities and autonomous regions across China as of December 31, 2019, covering approximately 1,900 Class III hospitals, approximately 17,000 other hospitals and medical institutions, as well as more than 200 large-scale national or regional pharmacy chains. Our leading commercial capabilities have enabled us to continuously procure our products’ entry into the NRDL as well as clinical practice guidelines and pathways. As of December 31, 2019, our existing product portfolio included over 20 products in the NRDL and over 10 products recommended in more than 40 clinical practice guidelines and pathways issued by government authorities or prestigious professional associations.

We currently have five PRC GMP certified production facilities for the manufacturing of our pharmaceutical products, including one located in Nanjing, Jiangsu Province, two located in Hainan Province, one located in Yantai, Shandong Province and one located in Wuhu, Anhui Province. Our production facilities house a total of 21 production lines for the production of biologics and small molecule pharmaceuticals in a variety of dosage forms including injectables, oral liquids, oral solid dosage forms (tablets, capsules, granules and powders), implants, gel and dry powder for inhalation, as well as five workshops for the production of APIs. We have received EU GMP certification or passed the U.S. FDA inspection for some of our production workshops. Moreover, we have a production facility for mAbs and other biologics in our pipeline, which is expected to commence pilot-scale production in June 2020. Furthermore, considering the complexity and difficulty in the manufacturing of cell therapy pharmaceuticals, we are currently constructing a new pilot-scale GMP-grade workshop for CMC and clinical research of the cell therapy pharmaceuticals in our product pipeline. We also plan to construct a new production facility for the commercial-scale production of cell therapy pharmaceuticals in our product pipeline in preparation for their commercial launch.

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## BUSINESS

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As the first pharmaceutical company with both biologics and small molecule drugs in China listed on the NYSE at the time when we were listed in 2007, we have made considerable progress over our 19 years of operating history as a dynamic pharmaceutical company. We subsequently privatized our Company in 2013. Over the years, we achieved significant growth. During the Track Record Period, our total revenue increased from RMB3,867.9 million in 2017 to RMB5,036.7 million in 2019, representing a CAGR of 14.1%. Our net profit increased from RMB350.4 million in 2017 to RMB1,003.6 million in 2019, representing a CAGR of 69.2%.

### OUR COMPETITIVE STRENGTHS

#### **Comprehensive and leading product portfolio focused in three large and fast-growing therapeutic areas with an increasing revenue contribution from innovative pharmaceuticals**

We have been strategically focusing on some of the largest and/or fastest growing therapeutic areas in China with significant unmet medical needs, including (i) oncology, (ii) central nervous system diseases and (iii) autoimmune diseases, with the mission of “providing today’s patients with medicines of the future.” We are one of the few pharmaceutical companies headquartered in China that have developed and launched two category I innovative pharmaceuticals, according to Frost & Sullivan. Our category I innovative pharmaceuticals, namely, Endostar and Iremod, contributed 21.4%, 25.5% and 32.9% of our total revenue for the years ended December 31, 2017, 2018 and 2019, respectively.

***Oncology.*** Our oncology product portfolio currently comprises five products, including our core oncology product, Endostar (recombinant human endostatin injection):

- Endostar is the first proprietary anti-angiogenic targeted drug in China and the only endostatin approved for sale in China and worldwide, according to Frost & Sullivan. It is also the first innovative biologics approved for sale in China as first-line treatment for NSCLC. Endostar was awarded the “Second Prize of the State Technological Innovation Award (國家技術發明二等獎)” and the “China Patents Gold Medal (中國專利金獎).” Endostar is clinically proven to be less toxic than conventional chemotherapy drugs and able to significantly extend advanced NSCLC patients’ median survival time and quality of life. Recombinant human endostatin has been included in the NRDL since 2017. Recombinant human endostatin is recommended as a first-line treatment for advanced NSCLC patients by a number of oncology clinical practice guidelines issued by the NHC, Chinese Medical Association (中華醫學會) and CSCO. In addition, Endostar has also shown superior efficacy in treatment of certain other tumors and complications, such as melanoma, osteosarcoma and malignant pleural effusion, and received wide recognition among healthcare professionals. Recombinant human endostatin is recommended as a first-line therapy for malignant melanoma and osteosarcoma by relevant clinical practice guidelines issued by CSCO.

According to Frost & Sullivan, in terms of sales revenue, the market for targeted therapy drugs for NSCLC in China grew at a CAGR of 40.8% from 2015 to 2019, reaching RMB20.8 billion in 2019. Recombinant human endostatin was the seventh best-selling category of targeted therapy drug for NSCLC in terms of sales revenue in 2019, with a market share of 5.9%, according to Frost & Sullivan.

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## BUSINESS

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**Central nervous system diseases.** Our central nervous system product portfolio currently comprises three products, including our core central nervous system product, Bicun (edaravone injection):

- Bicun is the first edaravone injection approved for sale in China and the second edaravone injection approved for sale worldwide, according to Frost & Sullivan. Edaravone has been recommended for the treatment of stroke by a number of clinical practice guidelines issued by Chinese Medical Association, the NHC, China Stroke Association (中國卒中協會), the Japan Stroke Society, the American Heart Association and the American Stroke Association.

According to Frost & Sullivan, in terms of sales revenue in 2019, the size of the edaravone drug market in China, being the third largest segment of the neuroprotective agent market in China, amounted to RMB2.9 billion. Bicun was the best-selling edaravone drug in terms of sales revenue in 2019, with a market share of 36.8%, according to Frost & Sullivan.

**Autoimmune diseases.** Our autoimmune product portfolio currently comprises four products, including our core autoimmune product, Iremod (iguratimod tablets):

- Iremod is the first iguratimod pharmaceutical product approved for sale in the world and the only iguratimod pharmaceutical product approved for sale in China, according to Frost & Sullivan. It is also the only PRC-developed small molecule DMARD that was launched in the past 10 years. Iguratimod has been included in the NRDL since 2017. Iguratimod is recommended as the primary therapy drug for treatment of active rheumatoid arthritis by a number of clinical practice guidelines and pathways issued by the NHC, Chinese Medical Association, Asia Pacific League of Associations for Rheumatology and the Ministry of Health, Labor and Welfare of Japan.

According to Frost & Sullivan, in terms of sales revenue, the conventional synthetic DMARD market in China grew at a CAGR of 12.4% from 2015 to 2019, reaching RMB3.1 billion in 2019. Iguratimod was the third best-selling conventional synthetic DMARD in terms of sales revenue in 2019, with a market share of 18.4%, according to Frost & Sullivan.

**Other therapeutic areas.** We also sell and/or promote a wide range of pharmaceutical products in cardiovascular diseases, anti-infective and other therapeutic areas.

- OLMETEC PLUS is a new-generation fixed-dose combination of an angiotensin II receptor blocker, olmesartan medoxomil, and a thiazide diuretic, hydrochlorothiazide, and an exclusive product in the PRC pharmaceutical market. Angiotensin II receptor blocker is the most prescribed category of anti-hypertensive pharmaceuticals worldwide, according to Frost & Sullivan.

## BUSINESS

- TB-PPD (purified protein derivative of tuberculin), an exclusive product, has been included in the “Industry Standards of the People’s Republic of China – Tuberculosis Diagnosis (WS288-2017)” (《中華人民共和國行業標準-肺結核診斷(WS288-2017)》) issued by the NHC.
- ZAILIKE-branded arbidol dispersible tablets, an exclusive dosage form, are a broad-spectrum anti-viral for treatment of influenza. Arbidol has been recommended by the NHC in its “Guidelines for the Diagnosis and Treatment of COVID-19 (Sixth/Seventh Editions for Trial Implementation)” (《新冠肺炎診療方案(試行第六版、第七版)》).

Compared with generic pharmaceuticals, innovative pharmaceuticals have higher technical barriers and enjoy first-mover advantages, well-positioning us in advancing our brand name and market position in the relevant therapeutic areas. In addition, we believe innovative pharmaceuticals are generally subject to more limited competition and relatively lower pricing pressure in centralized tender processes, enabling us to increase sales while maintaining stable profit margins.

While we have been committed to continuously increasing the contribution to our revenue from innovative pharmaceuticals, we have also been actively pursuing consistency evaluation approvals for our generic pharmaceuticals. Currently, we have obtained six consistency evaluation approvals for our generic pharmaceuticals, including Softan, ZAILIN-branded granules, ZAILIN-branded capsules and Biqi-branded diosmectite powder.

### Three near-commercial potential best-in-class therapies with significant market potential

Over the years, we have been continuously dedicated to our strategically focused three therapeutic areas, including, (i) oncology, (ii) central nervous system diseases and (iii) autoimmune diseases, increasing our investment in R&D on innovative drugs and collaborating extensively with external partners, with a view to further enhancing the competitiveness of our product portfolio. We currently expect to launch three key near-commercial products in 2020 and 2021 comprise:

- **Abatacept injection (阿巴西普注射液)**. Abatacept injection, which has obtained the IDL in China in January 2020, is the first innovative biologics developed by a PRC company jointly with a leading global pharmaceutical company that has been approved for sale in China, according to Frost & Sullivan. It is the first and only soluble CTLA4-Fc fusion protein approved for sale in China and the first and only selective T-cell co-stimulation modulator in the autoimmune disease therapeutic area worldwide, according to Frost & Sullivan. Abatacept injection is an innovative biologic drug candidate for the treatment of moderate to severe rheumatoid arthritis.

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## BUSINESS

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It may be used in combination with other DMARDs (other than TNF- $\alpha$  inhibitors), such as methotrexate, to treat moderate to severe active rheumatoid arthritis patients who do not respond favorably to other DMARDs. We believe abatacept injection distinguishes itself by the following core strengths:

- *Superior efficacy:* Abatacept injection is clinically proven to effectively improve the condition of rheumatoid arthritis patients, decrease their disease activity and enhance their quality of life. Due to CTLA4-Fc’s mechanism of action, we believe that abatacept injection has the potential to expand its indications to other autoimmune diseases in the future;
- *Proven safety profile:* According to a US claims database, the risk of hospitalized infection of patients who use abatacept injection was 22.6% lower than the commonly used TNF- $\alpha$  inhibitors; and
- *Better patient compliance:* We believe subcutaneous administration improves patient convenience and persistence with treatment.

Abatacept injection was developed by BMS and first approved for sale in the United States in 2005 under the Orencia® brand. It has also been launched in Europe and Japan with global sales of US\$3.0 billion in 2019, according to Frost & Sullivan, suggesting significant potential for this product candidate in China. According to Frost & Sullivan, in terms of sales revenue, the autoimmune biologics market is expected to grow from RMB5.8 billion in 2020 to RMB26.0 billion in 2024, with its share in the autoimmune pharmaceutical market increasing from 28.6% in 2020 to 48.9% in 2024. We expect to launch our abatacept injection in China in the third quarter of 2020, which will offer a novel and effective treatment option to rheumatoid arthritis patients in China. With the rapid increase in the sales of biologics in the PRC pharmaceutical industry, we believe the launch of our abatacept injection in China will further increase our market share in the autoimmune disease therapeutic area in China.

- *Edaravone and dexborneol concentrated solution for injection (依达拉奉右莰醇注射液用濃溶液).* Edaravone and dexborneol concentrated solution for injection is our category I innovative chemical drug candidate which we have been developing in-house over a period of 13 years and for which we possess proprietary intellectual property rights. We expect it to be the only drug for the treatment of stroke to obtain approval for sale in the past five years worldwide. We believe edaravone and dexborneol concentrated solution for injection distinguishes itself by the following core strengths:
- *Significantly higher efficacy than edaravone monotherapy:* A randomized, double-blind, positive controlled, head to head comparison phase III study in approximately 1,200 acute ischemic stroke patients has shown that, compared to edaravone monotherapy, edaravone and dexborneol concentrated solution for injection has significantly higher efficacy with similar safety profile, extending the therapeutic time window from 24 hours to 48 hours; and



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## BUSINESS

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- *Novel therapeutic mechanism:* Edaravone and dexborneol concentrated solution for injection is a novel neuroprotective agent that combines edaravone and dexborneol with a proven ratio of 4:1. Edaravone is an antioxidant and a free radical scavenger which scavenges hydroxyl free radical (OH), nitric oxide free radicals (NO) and peroxynitrite anion (ONOO<sup>-</sup>); while dexborneol is a bicyclic monoterpene which could inhibit the production or expression of pro-inflammatory cytokines such as TNF- $\alpha$  and interleukin-1 $\beta$  as well as inflammation-related proteins such as cyclo-oxygenase-2 and induced nitric oxide synthase. With its dual mechanism of action, edaravone and dexborneol concentrated solution for injection scavenges free radicals, inhibits inflammatory response and improves the permeability in blood-brain barrier, minimizing brain injury or impairment caused by acute ischemic stroke.

We expect to launch our edaravone and dexborneol concentrated solution for injection in China in the second half of 2020. According to Frost & Sullivan, stroke is the most common cause of adult death (accounting for 14.9% and 17.8%, respectively, of total deaths of urban and rural population in 2019) and disability in China with high risk of recurrence and an imperative need for more effective therapy. The prevalence of stroke in China is expected to grow from 16.6 million in 2020 to 19.8 million in 2024. We believe edaravone and dexborneol concentrated solution for injection has strong market potential to address significant unmet medical needs and its launch will further solidify our market leadership in the central nervous system therapeutic area in China.

- **KN035 (Envafolimab).** KN035, a PD-L1 inhibitor with differentiation advantages, is potentially the first subcutaneously injectable anti-PD-L1 monoclonal antibody worldwide. Our collaboration partners are currently conducting phase II clinical trials of KN035 for dMMR/MSI-H colorectal carcinoma and other advanced solid tumors and phase III clinical trials for advanced BTC in mainland China as well as phase I clinical trials in the United States and Japan. It is expected to submit the NDA in the second half of 2020 and launch in the PRC market in 2021. We believe KN035 distinguishes itself by the following core strengths:
  - As a subcutaneously injectable anti-PD-L1 monoclonal antibody, we believe that KN035 may reach a broader patient group and could be a more valuable option for patients with advanced solid tumors who are not suitable for intravenous infusion. If used in combination with oral medications, KN035 may free patients from the inconvenience of hospitalization;
  - KN035 is expected to be the first anti-PD-L1 monoclonal antibody for MSI-H solid tumors or BTC approved for sale in the PRC; and
  - With its unique molecule design and approximately half of the clinical dosage of other anti-PD-L1 monoclonal antibodies launched in the market, KN035 has shown similar efficacy and safety profile. In particular, according to the clinical data released at the 2020 annual meeting of the American Society of Clinical Oncology, KN035 has demonstrated an ORR of 34.0% for dMMR/MSI-H advanced solid tumors and an ORR of 54.2% in the colorectal

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## BUSINESS

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cancer patients who had prior therapy with fluoropyrimidine and oxaliplatin or irinotecan. In combination with FOLFOX, as a first-line therapy for advanced gastric cancer and gastroesophageal borderline tumor, the ORR is 60% and the median PFS is 6.8 months.

In March 2020, we entered into collaboration agreements with Jiangsu Alphamab and 3D Medicines Beijing, which have granted us an exclusive right to promote KN035 for all oncology indications in China. In addition to dMMR/MSI-H solid tumors and BTC, Jiangsu Alphamab and 3D Medicines Beijing are currently exploring opportunities to extend the indications of KN035 to other tumors. Meanwhile, we plan to collaborate with Jiangsu Alphamab and 3D Medicines Beijing to develop a number of combination therapies with KN035 for the treatment of solid tumors, in order to further enhance the competitiveness of KN035. According to Frost & Sullivan, the sales revenue of the PD-1/PD-L1 mAb market in China is expected to grow rapidly at a CAGR of 56.1% from RMB13.8 billion in 2020 to RMB81.9 billion in 2024. We expect KN035 has vast market potential and its launch will complement our oncology product portfolio and continue to allow us to capture market share in the oncology pharmaceutical market in China.

### **Robust product pipeline driven by our in-house R&D efforts and R&D collaborations**

Since our inception, we have been committed to developing innovative pharmaceuticals with clinical advantages and have been increasing our investment in R&D. For the years ended December 31, 2017, 2018 and 2019, our research and development costs accounted for 5.5%, 9.9% and 14.2%, respectively, of our total revenue for the same periods. Leveraging our continuous R&D efforts over the years, we have established three integrated R&D centers, including one in Nanjing, Jiangsu, one in Shanghai and one in Boston, the United States. With the approval of the Ministry of Science and Technology, we have established a national key laboratory. As of December 31, 2019, our R&D department consisted of 699 full-time employees, 292 of whom held master’s degrees and 113 held Ph.D. degrees, featuring project leaders for NHFPC’s “Major New Drug Creation” Science and Technology Major Projects (「重大新藥創制」科技重大專項). Over 10% of our employees in R&D department are scientists or former R&D personnel from overseas well-known pharmaceutical companies or universities.

In addition, we collaborate extensively with domestic and international R&D partners to develop innovative drug candidates that fit our business strategies. Capitalizing on our in-house R&D capabilities, proven track record of successful development and commercialization of innovative pharmaceuticals, combined with our established manufacturing and commercial capabilities, we believe we are an attractive partner of choice for domestic and international pharmaceutical companies and biotechnology companies seeking to unlock the value of their assets in the rapidly growing PRC pharmaceutical market. We are one of the few companies in China to have developed and obtained NDA for two category I innovative pharmaceuticals, IDL for one imported innovative pharmaceutical and have one additional category I innovative pharmaceutical with NDA pending, according to Frost & Sullivan.

Our vigorous in-house R&D efforts and extensive R&D collaborations have translated into a robust pipeline of product candidates in oncology, autoimmune disease and central nervous system disease therapeutic areas, addressing significant unmet medical needs. In



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## BUSINESS

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particular, we actively pursue opportunities to develop cell therapy pharmaceuticals, which is consistent with our mission of “providing today’s patients with medicines of the future.” Compared to conventional therapies, the revolutionary cell therapy has the potential to offer curative treatment to patients with hematologic malignancies such as non-Hodgkin’s lymphoma and acute lymphoblastic leukemia.

### *Oncology*

Our oncology product candidates primarily focus on solid tumors and hematologic malignancies, including (i) monoclonal antibodies with a number of angiogenesis inhibitors, which will not only further solidify our market position in the relevant sectors, and also enable us to explore combination therapies with immune checkpoint inhibitors; and (ii) small molecule drugs that target cancer driver genes. Our key oncology product candidates include:

- ***Bevacizumab (貝伐珠單抗)***: We are collaborating with Amgen for the development of our biosimilar product candidate to Avastin®, a bevacizumab. We have obtained the IND approval for this product candidate and currently, we are conducting the randomized, double-blind pivotal registrational trials of this product candidate in China for treatment of advanced non-squamous NSCLC. We expect to file the IDL application for this product candidate in China in 2022. The global sales of Avastin® reached US\$7.12 billion in 2019, according to Frost & Sullivan, while bevacizumab biosimilars have been launched in Europe and the United States.
- ***Sevacizumab (賽伐珠單抗)***: We are collaborating with Apexigen for the development of sevacizumab, a new-generation recombinant humanized anti-VEGF monoclonal antibody. In its pre-clinical studies, sevacizumab has shown higher tumor suppression efficacy in multiple cancer models, compared to bevacizumab at the same dose. We are currently conducting phase I clinical trials of this product candidate in China for the treatment of ovarian cancer and the preliminary results have shown a favorable safety profile and early efficacy signals. We plan to initiate phase II/III clinical trials of this product candidate in China in 2021.
- ***PEG-ENDO (Pegylated recombinant human endostatin for injection)***: PEG-ENDO is a biologic drug candidate which modifies recombinant human endostatin by conjugation with a methoxy polyethylene glycol aldehyde, enhancing its pharmacokinetic properties while retaining its biological activities. Pharmacodynamic studies in animal models have demonstrated that PEG-ENDO can significantly enhance the effects of chemotherapy in multiple cancer models when used in combination with chemotherapy drugs. We are currently conducting phase Ib clinical trials for this product candidate in China.
- ***SIM-201***: SIM-201 is a second-generation NTRK gene fusion inhibitor which we have been developing in-house, potentially targeting primary mutation to NTRK, ROS1 and ALK as well as secondary resistance mutation to NTRK and ROS1. We have submitted the IND application for this product candidate.

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## BUSINESS

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- **SIM-323:** We are collaborating with GI Innovation for the development of SIM-323, which is expected to alleviate immunosuppression while activating anti-neoplastic immunoreaction. We plan to submit the IND application for this product candidate in China in 2021.

### *Cell therapy*

We are a large-scale vertically integrated pharmaceutical company that strategically targets cell therapy sector. Recently, there has been an increasing trend to test cell therapy in cancer treatment, which is potentially a revolutionary and curative treatment approach for some of the patients. In the long-term, with the advancement of cell preparation as well as gene editing and delivery technologies, we expect the next 10 years to be a flourishing period for cell therapy. We believe cell therapy has promising prospects and have made strategic moves to tap into opportunities in the market to further expand the breadth of our oncology product pipeline, mainly attributable to its:

- *Significant potential to cure certain types of cancer:* Two CAR T-cell therapy pharmaceuticals approved for sale in the United States, namely, Yescarta and Kymriah, have shown high remission rates in patients with r/r B-cell tumors and outstanding long-term survival rates; and
- *Relatively short development cycle:* Due to its precise treatment mechanism and superior efficacy, with a relatively small number of enrolled patients for clinical trials, cell therapy pharmaceuticals generally can use phase II clinical trials as the pivotal trials for NDA submission, resulting in market launch within a short period of time.

Therefore, we believe cell therapy will become an important development trend for the oncology therapeutic area. We have quickly begun strategic planning and allocation of resources to capitalize on such trend, striving for continuous innovation in this sector. As of the Latest Practicable Date, we had more than 10 cell therapy product candidates, among which three CAR T-cell therapy candidates had obtained IND approval and one is preparing for the IND application. We are collaborating with external R&D partners for the development of these three autologous CAR T-cell therapy candidates with IND approval, which have shown efficacy in investigator-initiated clinical trials. Such three CAR T-cell therapy candidates comprise:

- **CD19 CAR T-cell Therapies:** We are developing two CD19 CAR T-cell therapies for the treatment of r/r CD19 positive B-cell non-Hodgkin's lymphoma and r/r CD19 positive B-cell acute lymphoblastic leukemia. Investigator-initiated clinical trials for lymphoma have shown a 6-month ORR of 53% and the median PFS of nine months, which are comparable to Yescarta and Kymriah. We plan to initiate phase I clinical trials in China in the second half of 2020 and expect to submit the NDA in 2022. In addition, we intend to further expand its indications to other oncology diseases such as mantle cell lymphoma.

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## BUSINESS

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- **BCMA CAR T-cell Therapy:** We are developing BCMA CAR T-cell therapy for the treatment of r/r multiple myeloma, which is expected to be the first humanized single domain antibody at clinical stage in China with the fastest development progress worldwide, according to Frost & Sullivan. Investigator-initiated clinical trials have shown an ORR of 88% and a CR of over 50% on patients with r/r myeloma, which are comparable to the data released by similar products under development around the world. We plan to initiate phase I clinical trials in China in 2020 and expect to submit the NDA in 2023.

We also plan to perform clinical trials to explore opportunities to use these three CAR T-cell therapy candidates in the treatment of second-line and even first-line high-risk patients. We are also considering to develop combination therapies with other immune checkpoint inhibitors, immune agonists or targeted therapy drugs in our product pipeline, with the aim of further enhancing the efficacy of these three CAR T-cell therapy candidates.

In addition to hematologic malignancies, we are developing in-house or in collaboration with R&D partners autologous cell therapy pharmaceuticals for the treatment of solid tumors, such as HPV16/18 positive cervical cancer, glioblastoma and liver cancer.

Moreover, we are also actively engaged in research to explore opportunities to develop universal allogeneic cell therapies, such as gene-edited universal allogeneic CAR-T cells as well as other immune cells such as NKT cells and NK cells, for the treatment of various solid tumors.

Considering the complexity and difficulty in the manufacturing of cell therapy pharmaceuticals, we are currently constructing a new pilot-scale GMP-grade workshop for CMC and clinical research of the cell therapy pharmaceuticals in our product pipeline. We also plan to construct a new production facility for the commercial-scale production of cell therapy pharmaceuticals in our product pipeline in preparation for their commercial launch.

Furthermore, we are an early-stage investor in certain emerging biotechnology companies specializing in cell therapy, such as Nanjing Bioheng Biotech Co., Ltd., AffyImmune Therapeutics and Carmine Therapeutics. We believe such strategic partnerships will enable us to further advance our innovation in the cell therapy sector.

### ***Central nervous system diseases***

Our central nervous system product candidates aim to offer full-cycle medications for patients with stroke, from the relief and early treatment of mild to moderate acute stroke, maintenance treatment after patient discharge, and to treatment of cerebral edema caused by severe stroke. Our key central nervous system product candidates include:

- **Y-2 sublingual tablets (Y-2 舌下片):** Y-2 sublingual tablets are the solid dosage form of edaravone dexborneol compound. Sublingual administration of this compound inhibits inflammation and improves the permeability in the blood-brain barrier, minimizing brain injury or impairment caused by acute ischemic stroke. Sequential

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## BUSINESS

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therapy consisting of Y-2 sublingual tablets and edaravone and dexborneol concentrated solution for injection is designed to enable patients to receive a timely and complete treatment. In addition, administration of sublingual tablets is less dependent on medical conditions or compliance of patients, which makes it more suitable for research on new indications such as other chronic central nervous system diseases. We are currently conducting phase I clinical trials for this product candidate in China; while YenePharma, our collaboration partner, is conducting phase I clinical trials for the this product candidate in the United States. We expect to initiate phase II clinical trials for this product candidate in China in 2021.

- **SIM-307:** SIM-307 is a first-in-class chemical compound developed based on the Nobel-prize winning water channel discovery. Studies have demonstrated SIM-307 as an AQP4 inhibitor to be effective in control of cerebral edema. SIM-307 is intended for treatment of cerebral edema caused by acute ischemic stroke through intravenous infusion administration. We are responsible for the development and commercialization of SIM-307 in the Greater China and we expect to initiate phase I clinical trials for it in China in 2021. Aeromics, our collaboration partner, has completed phase I clinical trial for the same in the United States.

### *Autoimmune diseases*

Our autoimmune product candidates consist of both new drugs and existing drugs with new indications, targeting major indications that have significant unmet medical needs, including rheumatoid arthritis, Sjögren’s syndrome, psoriasis and gout. Our key autoimmune product candidates include:

- **SIM-335:** SIM-335, an innovative chemical drug candidate which we have been developing in-house, is intended for the treatment of mild to moderate plaque psoriasis through topical administration. We have obtained IND approval for this product candidate in China and are currently preparing for phase I clinical trials.
- **Iguratimod tablets (Sjögren’s syndrome) (艾拉莫德片(干燥综合征)):** Iguratimod tablets, a chemical drug candidate, are intended for the treatment of primary Sjögren’s syndrome by inhibiting the generation of inflammatory cytokines and stimulating the generation of immunoglobulins. According to investigator-initiated clinical trials, iguratimod tablets, when used in combination with methylprednisolone, have demonstrated higher efficacy and faster onset than conventional therapy of using hydroxychloroquine in combination with methylprednisolone, without increased incidence of adverse events. Iguratimod tablets have been recommended by the “Primary Sjögren’s Syndrome Diagnosis and Treatment Standards” (《原发性干燥综合征诊疗规范》) issued by the Chinese Medical Doctor Association (中國醫師協會) in 2020. We are currently preparing for the IND application for this product candidate in China.

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## BUSINESS

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- **SIM-295:** SIM-295, an innovative chemical drug candidate, is a selective URAT1 inhibitor intended for the treatment of gout with hyperuricemia. We are responsible for the development and commercialization of SIM-295 in mainland China, Hong Kong and Macau. JW Pharmaceutical, our collaboration partner, is conducting phase IIb clinical trials for SIM-295 in South Korea, which have observed promising efficacy and favorable safety profile. We are currently preparing for the IND application for this product candidate in China.

In addition to the above-mentioned product candidates, in the three therapeutic areas we strategically focus on, we have over 30 innovative drug candidates that are in pre-clinical studies.

### **Leading commercial capabilities with nationwide sales and distribution network**

We maintain a nationwide sales and distribution network, which, combined with our leading commercial capabilities, have been among the key drivers for our continuously increasing revenue contribution from innovative pharmaceuticals. As of December 31, 2019, we had over 2,600 sales and marketing personnel spanning 31 provinces, municipalities and autonomous regions across China, covering approximately 1,900 Class III hospitals, approximately 17,000 other hospitals and medical institutions, as well as more than 200 large-scale national or regional pharmacy chains across China. As of the same date, our core sales and marketing personnel had an average of over 10 years of pharmaceutical industry-related experience, and over 40% of them held bachelor’s degrees or above in medicine, pharmacy or related majors. Our leading commercial capabilities are reflected in our comprehensive and effective marketing support system. In particular, our medical market department (醫學市場部) at the headquarters level is responsible for developing the overall sales and marketing strategies for each of our products and procuring our products’ entry into a wide range of clinical practice guidelines and pathways. As of December 31, 2019, our existing product portfolio included over 10 products recommended in more than 40 clinical practice guidelines and pathways issued by government authorities or prestigious professional associations. In addition, our strategic account department (戰略客戶部) at the headquarters level analyzes applicable laws and regulations, formulating corresponding strategies, and when suitable opportunities arise, procuring our products’ entry into the NRDL or other government-sponsored medical insurance programs. As of December 31, 2019, our existing product portfolio included over 20 products included in the NRDL. We provide systematic professional trainings to our skilled in-house sales force, which enables them to accurately and effectively convey the therapeutic benefits and strengths of our products when communicating with healthcare professionals.

We believe that our effective commercial capabilities will allow us to not only continue to enhance market awareness and penetration of our existing products, but also pursue partnerships and strategic alliances with domestic and international pharmaceutical and biotechnology companies, providing a solid foundation for the continued expansion of our business. In addition, our sales and marketing team are involved in our entire R&D process, which enables us to focus on R&D projects with unmet medical needs and great market potential and advance our R&D projects in an efficient manner.



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## BUSINESS

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### **World-class manufacturing infrastructure and quality control standards**

We currently have five production facilities, including one located in Nanjing, Jiangsu Province, two located in Hainan Province, one located in Yantai, Shandong Province and one located in Wuhu, Anhui Province. Our production facilities house a total of 21 production lines for the production of biologics and small molecule pharmaceuticals in a variety of dosage forms including injectables, oral liquids, oral solid dosage forms (tablets, capsules, granules and powders), implants, gel and dry powder for inhalation, as well as five workshops for the production of APIs. These production lines and workshops were established and have been operated in compliance with PRC GMP standards. We have received EU GMP certification or passed the U.S. FDA inspection for some of our production workshops. Moreover, we have a production facility for mAbs and other biologics in our pipeline, which is expected to commence pilot-scale production in June 2020.

We have implemented comprehensive quality control procedures and protocols that span across the entire production lifecycle from raw material sourcing till the final products are delivered to customers. We believe our global-standard manufacturing infrastructure, combined with our stringent quality control practices, enable us to produce high quality products consistently and efficiently.

### **A visionary senior management team with a strong sense of mission and proven track record**

We are led by an open-minded senior management team with in-depth and complementary knowledge and expertise and global vision. Our senior management team has extensive R&D and collaboration experience, guiding and supporting our rapid transition to an innovation and R&D-driven pharmaceutical company.

Mr. Ren, our founder, chairman of the Board and chief executive officer, has over 30 years of industry experience and entrepreneurial experience in the PRC pharmaceutical market. Mr. Ren is currently the head of our national key laboratory of translational medicine and innovative pharmaceuticals (轉化醫學與創新藥物國家重點實驗室), the vice president of the China Pharmaceutical Innovation Promotion Association (中國醫藥創新促進會) and the vice chairman of the Ninth Committee of Jiangsu Science and Technology Association (江蘇省科學技術協會第九屆委員會).

Other members of our senior management team possess an average of over 20 years of industry experience in China and abroad, collectively covering a full spectrum of skillsets from research development, manufacturing to commercialization. In particular:

Mr. WANG Pin, our chief science officer, obtained a Ph.D in chemical engineering from California Institute of Technology and was previously the director of the center for immunoengineering in the University of Southern California. Since March 2015, he has been a full professor of the chemical engineering and materials department and biomedical engineering department of the University of Southern California, where he has also been the Zohrab A. Kaprielian Fellow in the chemical engineering and materials department. Mr. WANG Pin has achieved remarkable accomplishments in cell and gene therapy.

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## BUSINESS

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Mr. TANG Renhong, our senior vice president and executive Director, obtained a Ph.D. in molecular cell biology from Nanyang Technological University and was a postdoctoral researcher at the University of California, San Francisco. Mr. TANG Renhong previously served managerial positions in a number of global pharmaceutical companies where he was extensively involved in the R&D of innovative pharmaceuticals.

We believe that the strong sense of mission, as well as the complementary skills and experience, of our senior management team will continue to lead our nearly 5,000 employees, contributing to the well-being of patients.

### OUR STRATEGIES

We aim to continue to solidify market leadership in our strategically focused therapeutic areas in China. Over the long-term, our objective is to become a leading innovation and R&D-driven pharmaceutical company in China. We plan to implement the following strategies to achieve our goal:

#### **Continue to invest in R&D and rapidly advance the development of our product candidates**

We believe continuous innovation is critical to our competitiveness and sustainable growth. We intend to continue to invest in R&D and focus on oncology, central nervous system disease and autoimmune disease therapeutic areas where we have already established a leading product portfolio and extensive R&D experience.

We will continue to actively advance the development of our product candidates. In the next two or three years, we expect to have two innovative product candidates to submit NDA in China, one biosimilar candidate to submit IDL application in China, five innovative product candidates to initiate phase II or III clinical trials in China, six innovative product candidates to initiate phase I clinical trials in China and at least nine innovative product candidates to submit IND applications in China. For example:

- ***Oncology.*** We expect to submit the NDA/IDL application for our two CD19 CAR T-cell therapy candidates and bevacizumab biosimilar candidate. We expect to complete the phase I clinical trials for sevacizumab and initiate phase II/III clinical trials. We also expect to initiate phase II clinical trials for PEG-ENDO and BCMA CAR T-cell therapy. In addition, we plan to initiate phase I clinical trials for SIM-201 and subcutaneous PD-L1 nanobody combination therapy candidates.
- ***Central Nervous System diseases.*** We expect to complete the phase I clinical trials for Y-2 sublingual tablets and initiate II clinical trials. We also plan to initiate phase I clinical trials for SIM-307 and SIM-339.

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## BUSINESS

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- ***Autoimmune diseases.*** We plan to initiate phase I clinical trials for SIM-295. We also plan to initiate phase II clinical trials of Sjögren’s syndrome indication for Iremod and SIM-335.

We expect the commercialization of these product candidates to further enhance our product portfolio and market penetration in the relevant therapeutic areas.

### **Continue to source innovative therapies globally and expand our extensive R&D network**

In addition to relying on our in-house R&D team, we plan to continue our innovative R&D efforts through R&D collaborations. In particular, we plan to focus on procuring drug candidates that have initiated Phase II/III clinical trials or revolutionary technologies and drug candidates that are still in early stage for commercialization in China.

We intend to leverage our global business development team and R&D team to continue to proactively pursue and evaluate collaboration opportunities with additional R&D partners. Meanwhile, we will take advantage of our investments in well-known healthcare investment funds such as MPM Capital and Ally Bridge Group. We believe such investments will broaden our access to potential R&D collaboration opportunities as well as diverse and competitive drug candidates.

### **Continue to attract and develop the best talent and strengthen our human capital**

We believe our team of talent is key to our success. We plan to implement the following initiatives:

- ***Nurture and empower highly skilled talent:*** We will continue to offer our employees a platform supporting continuous self-learning and self-development. We aim to maximize the potential of our talent through rotation, objective and key results (OKR) management and comprehensive trainings.
- ***Recruit promising talent:*** In line with our rapid transition to an innovation and R&D-driven pharmaceutical company, we will continue to attract and recruit promising talent in our core business areas and increase our talent density, with a focus on specialists in the research and development of innovative pharmaceuticals.
- ***Optimize organizational structure:*** We plan to continuously optimize our decision-making and incentive schemes and promote our high-performance corporate culture that values employees taking initiative, with a view to further solidifying our competitive advantages.

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## BUSINESS

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### **Continue to expand our market access and strengthen our sales and marketing capabilities**

We are committed to strengthening our highly specialized sales and marketing network and will continue to expand and empower our skilled in-house sales force, in order to support the launch of new products in the future and to deepen our market penetration, thus further increasing our revenue contribution from innovative pharmaceuticals.

We aim to further increase the accessibility of our existing products to continue to unleash their market potential. Meanwhile, we will invest in the marketing and promotion of our new products to facilitate their market launch. We will also continue to enhance our marketing efforts, including strengthening academic partnerships with large hospitals, to increase public awareness of our products and further solidify our brand name. In addition, in response to the PRC government’s efforts to develop a tiered diagnosis and treatment system, we will further expand our marketing channels and increase our coverage of hospitals at the community or county level.

### **Further enhance our GMP-compliant manufacturing capabilities**

We are committed to continuously improving our production facilities and quality control practices. We will continue to establish new production facilities and production lines in accordance with international GMP standards and NMPA requirements, and invest in state-of-the-art production equipment. We also plan to leverage our strong track record and experience in manufacturing and quality control management to obtain GMP certifications for addition production lines and workshops. In addition, we have three new injection production lines under construction that are designed in accordance with international GMP standards. Moreover, we are currently constructing a new pilot-scale GMP-grade workshop for CMC and clinical research of the cell therapy pharmaceuticals in our product pipeline. We also plan to construct a new production facility for the commercial-scale production of cell therapy pharmaceuticals in our product pipeline in preparation for their commercial launch. Please see “– Production – Production Facilities – Expansion Plan” for more details.

## **OUR PRODUCT PORTFOLIO**

### **Our Existing Product Portfolio**

With our continuous growth over the years, we have established a diversified product portfolio comprising:

- Oncology: five products for the treatment of oncology diseases, under Endostar, Jepas, Jiebaili, Sinofuan and another brand;
- Central nervous system diseases: three products under Bicun (for the treatment of stroke) and other brands;

## BUSINESS

- Autoimmune diseases: four products for the treatment of active rheumatoid arthritis and pain caused by rheumatoid arthritis and osteoarthritis, under Iremod, Yingtaiqing and other brands;
- Cardiovascular diseases: three products for the treatment of cardiovascular diseases such as high triglycerides and high blood pressure, under Softan, OLMETEC PLUS and another brand;
- Anti-infective: 15 products for the treatment of bacterial or virus-related infectious diseases, under Newanti, ZAILIN, ZAILIKE and other brands; and
- A number of products for the treatment of other diseases, such as Biqui-branded diosmectite powder and dispersible tablets, our anti-diarrhea products.

We also manufacture and sell a number of APIs, such as diosmectite.

The following table sets forth a breakdown of our revenue from sales of pharmaceutical products by therapeutic areas for the periods indicated:

	Year ended December 31,					
	2017		2018		2019	
	RMB'000	%	RMB'000	%	RMB'000	%
Oncology products	1,004,855	26.2	1,279,801	29.7	1,568,853	32.7
Central nervous system products	1,276,142	33.3	1,202,008	27.9	936,869	19.5
Autoimmune products	423,219	11.0	537,849	12.5	813,786	17.0
Cardiovascular products	243,432	6.3	353,082	8.2	445,468	9.3
Anti-infective products	564,699	14.7	579,476	13.4	635,719	13.2
Others <sup>(1)</sup>	324,632	8.5	356,932	8.3	399,628	8.3
<b>Total</b>	<b>3,836,979</b>	<b>100.0</b>	<b>4,309,148</b>	<b>100.0</b>	<b>4,800,323</b>	<b>100.0</b>

*Note:*

- (1) Including pharmaceutical products for the treatment of other diseases, APIs and other healthcare products.



## BUSINESS

The following table sets forth the sales of our major products in terms of revenue contribution in absolute amounts and as percentages of our total revenue for the periods indicated:

	2017		Year ended December 31, 2018		2019	
	<i>RMB'000</i>	<i>% of revenue</i>	<i>RMB'000</i>	<i>% of revenue</i>	<i>RMB'000</i>	<i>% of revenue</i>
Endostar	669,662	17.3	856,830	19.0	1,136,547	22.6
Bicun	1,244,176	32.2	1,198,595	26.6	936,901	18.6
Iremod	159,025	4.1	291,687	6.5	520,157	10.3
Softan	179,152	4.6	277,666	6.2	334,852	6.6
Yingtaiqing <sup>(1)</sup>	261,533	6.8	242,832	5.4	289,912	5.8
Newanti	257,138	6.6	258,184	5.7	283,907	5.6
ZAILIN	189,163	4.9	187,427	4.2	199,706	4.0
Jepaso	132,909	3.4	162,361	3.6	173,104	3.4
Sinofuan	116,582	3.0	115,710	2.6	128,265	2.5
Jiebaili	85,664	2.2	144,833	3.2	127,033	2.5
<b>Total major products</b>	<b>3,295,004</b>	<b>85.1</b>	<b>3,736,125</b>	<b>83.0</b>	<b>4,130,384</b>	<b>81.9</b>

*Note:*

- (1) Including sales of Yingtaiqing-branded diclofenac sodium sustained-release capsules sourced from CPU Pharma as well as Yingtaiqing-branded diclofenac sodium sustained-release capsules and Yingtaiqing-branded diclofenac sodium gel manufactured by us.

## BUSINESS

The following table sets forth selected information of our major products as of the Latest Practicable Date:

Therapeutic area	Major product	Classification	Indication(s)	Year of approval for sales in China	OTC/prescription pharmaceutical	Expiration date of production approval	Status of consistency evaluation <sup>(1)</sup>	Specifications	NRDL <sup>(2)</sup>	National Essential Drug List <sup>(3)</sup>
Oncology:	Endostar (recombinant human endostatin injection)	Category I innovative pharmaceutical	NSCLC	2005	Prescription	November 12, 2024	N/A	15mg/2.4x105U/3ml per pre-filled syringe	Yes, Part B	No
	Jepaso (nedaplatin for injection)	First-to-market generic pharmaceutical	Solid tumors	2003	Prescription	July 21, 2020	Application filed	10mg per vial	Yes, Part B	No
	Jiebaoli (pemetrexed disodium for injection)	Generic pharmaceutical	Non-squamous NSCLC; pleural mesothelioma	2009	Prescription	March 12, 2024	Application filed	0.1g/0.2g/0.5g per vial	Yes, Part B	Yes
	Sinofuan (5-fluorouracil implants)	New formulation drug	Digestive system tumors	2003	Prescription	September 28, 2024	N/A	0.1g per vial	No	No
	Bicun (edaravone injection)	First-to-market generic pharmaceutical	Cerebral infarction	2003	Prescription	July 28, 2020	Application filed	5ml:10mg/20ml:30mg per ampoule	No	No
Central nervous system diseases:										
Autoimmune diseases:	Iremod (iguratimod tablets)	Category I innovative pharmaceutical	Active rheumatoid arthritis	2011	Prescription	June 16, 2021	N/A	25mg per pill	Yes, Part B	No
	Yingqiaqing (diclofenac sodium sustained-release capsules <sup>(4)</sup> /gel)	First-to-market generic pharmaceutical (for capsules)/Generic pharmaceutical (for gel)	Pain relief	2005 (for gel) <sup>(4)</sup>	Prescription (for capsules)/OTC (for gel)	July 2, 2020 (for gel) <sup>(4)</sup>	-	50mg per pill (for capsules)/0.15g/0.20g/0.05g per tube (for gel)	Yes, Part A (for capsules)/No (for gel)	Yes (for capsules)/No (for gel)
Cardiovascular diseases:	Softan (rosuvastatin calcium tablets)	Generic pharmaceutical	High cholesterol	2011	Prescription	January 21, 2021	Passed in October 2018 (10mg) and March 2019 (5mg)	5mg/10mg per pill	Yes, Part B	Yes

## BUSINESS

Therapeutic area	Major product	Classification	Indication(s)	Year of approval for sales in China	OTC/prescription pharmaceutical	Expiration date of production approval	Status of consistency evaluation <sup>(1)</sup>	Specifications	NRDL <sup>(2)</sup>	National Essential Drug List <sup>(3)</sup>
Anti-infectives:	Newanti (biapenem for injection)	First-to-market generic pharmaceutical	Bacterial infections	2008	Prescription	December 10, 2022	Application filed	0.3g per vial	Yes, Part B	No
	ZAILIN (amoxicillin granules/dispersible tablets/capsules)	Generic pharmaceutical	Bacterial infections	1993 (for granules)/2002 (for tablets)/1996 (0.25g) (for capsules)	Prescription	May 7, 2025 (for granules)/ April 8, 2024 (for tablets)/ May 7, 2025 (0.25g) (for capsules)	Passed in September 2019 (for granules)/ Passed in November 2019 (for capsules)	0.125g per pack (for granules)/ 0.25g per pill (for tablets)/ 0.25g per pill (for capsules)	Yes, Part A	Yes

### Notes:

- (1) Our generic pharmaceuticals which had been approved for sale before the implementation of the “Reform Plan for Registration Classification of Chemical Pharmaceuticals 《化學藥品註冊分類改革工作方案》” are required to undergo and pass the consistency evaluation pursuant to the relevant PRC regulations. In particular, all generic pharmaceuticals which are among our major products are required to complete the consistency evaluation within three years from the date the first generic pharmaceutical of the same variety (namely, of the same generic name, the same dosage form, the same specifications and the same indications) has passed the consistency evaluation. We may apply for an extension with the NMPA at the provincial level if we have assessed and considered that the relevant generic pharmaceuticals are of limited market availability and have unmet clinical demand, and the NMPA at the provincial level may grant the appropriate extension after evaluation and consultation with the provincial public health administrative authorities. Please see “Regulatory Overview – Laws and Regulations on Drug Distribution – Registration of Generic Drugs” for more details. The manufacturer of the generic pharmaceutical of the same variety as ZAILIN has filed the application for consistency evaluation.
- (2) The NRDL comprises Part A and Part B. Patients purchasing pharmaceuticals included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price, while patients purchasing pharmaceuticals included in Part B of the NRDL are required to pay a deductible amount and obtain reimbursement for the remainder of the purchase price. The amount of the deductible differs from region to region in the PRC. Please see “Regulatory Overview – Laws and Regulations on Drug Distribution – National Medical Insurance Program” for more details.
- (3) Please see “Regulatory Overview – Laws and Regulations relating to Drugs – National Essential Drug List” for more details about the National Essential Drug List.
- (4) The Yingtaiqing-branded sustained-release capsules that we current sell and/or promote are produced by and sourced from CPU Pharma. However, pursuant to our non-competition undertaking to CPU Pharma which is in line with our general practice for other third-party pharmaceutical products, we agreed not to produce diclofenac sodium sustained-release capsules unless necessary to meet the requirements of PRC laws and regulations. Please see “– Autoimmune Products – Yingtaiqing (Diclofenac Sodium) 英太青® (雙氯芬酸鈉)” for more details. Therefore, certain information regarding Yingtaiqing-branded sustained-release capsules are not disclosed in the table above.

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## BUSINESS

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### *Oncology Products*

Our oncology product portfolio currently comprises five products, including four of our major products: Endostar, Jepasol, Jiebaoli and Sinofuan. For the years ended December 31, 2017, 2018 and 2019, our sales of oncology products were RMB1,004.9 million, RMB1,279.8 million and RMB1,568.9 million, respectively, accounting for 26.2%, 29.7% and 32.7% of our revenue from sales of pharmaceutical products for the same periods, respectively.

According to Frost & Sullivan, oncology was the 5th largest therapeutic area in China in terms of sales revenue of pharmaceuticals in 2019, accounting for 11.2% of the overall pharmaceutical market in the same year. In terms of sales revenue, the oncology pharmaceutical market grew at a CAGR of 13.5% from RMB110.2 billion in 2015 to RMB182.7 billion in 2019, and is expected to grow further at a CAGR of 15.4% from 2020 to 2024, reaching RMB367.2 billion in 2024. The significant unmet clinical demands, increase in patients’ affordability and willingness to pay for treatment, favorable government policies to support the development of innovative pharmaceuticals as well as combination therapies will continue to drive the rapid growth of the oncology pharmaceutical market in China, according to Frost & Sullivan.

*Endostar (Recombinant Human Endostatin) 恩度® (重組人血管內皮抑制素)*

*Innovative biologics, included in the NRDL, the only endostatin approved for sale worldwide*

Endostar (recombinant human endostatin injection), our category I innovative biologic drug, is the first proprietary anti-angiogenic targeted drug in China and the only endostatin approved for sale in China and worldwide, according to Frost & Sullivan. It is also the first innovative biologics approved for sale in China as first-line treatment for NSCLC. Recombinant human endostatin is a genetically engineered protein that inhibits the growth of blood vessels to a tumor, thereby slowing and preventing the growth and metastasis of tumor cells. Endostar is a targeted cancer therapy drug which, in combination with NP chemotherapy regimen, can be used to treat early and recurrent stage III/IV NSCLC. Our phase III clinical trials, completed in 2004, demonstrated that, compared with NP chemotherapy regimen alone, combining Endostar with NP chemotherapy regimen can significantly extend advanced NSCLC patients’ median time to progression (TTP) and overall survival (OS) and improve their quality of life. We commenced our phase IV post-marketing clinical trials in 2006, enrolling an aggregate of 2,725 subjects. According to our phase IV clinical trials, combining Endostar with other different first-line chemotherapies, including NP regimen, gemcitabine/cisplatin (GP) regimen, paclitaxel/carboplatin (TC) regimen and docetaxel and cisplatin (DP) regimen, could all slow down disease progression in advanced NSCLC patients (median time to progression (TTP) of 7.6 months and median OS of 17.6 months) with a favorable safety profile. In addition, trial results did not demonstrate a significant difference in efficacy among the four groups of Endostar-combined chemotherapy.

## BUSINESS

Recombinant human endostatin is recommended by a number of oncology clinical practice guidelines in China as a first-line therapy for advanced NSCLC patients. In particular, it has been recommended by the “Primary Lung Cancer Diagnosis and Treatment Standards” (《原发性肺癌诊疗规范》) issued by NHC in 2015 and 2018, the “Clinical Pathways for NSCLC (2016)” (《非小细胞肺癌化疗临床路径(2016版)》) issued by the NHC, the “Chinese Medical Association Guideline for Clinical Diagnosis and Treatment of Lung Cancer (2018)” (《中华医学会肺癌临床诊疗指南(2018版)》) issued by the Chinese Medical Association, the “Guidelines of Chinese Society of Clinical Oncology (CSCO) Primary Lung Cancer (2019)” (《中国临床肿瘤学会原发性肺癌诊疗指南(2019版)》) and the “Chinese Expert Consensus on Anti-angiogenic Drugs for Advanced NSCLC (2019)” (《晚期非小细胞肺癌抗血管生成药物治疗中国专家共识(2019版)》) issued by the CSCO. Moreover, recombinant human endostatin has been recommended as a first-line therapy for malignant melanoma and osteosarcoma by relevant clinical practice guidelines issued by the CSCO.

As of the Latest Practicable Date, we held one invention patent on the compound of Endostar in the United States, which was valid until 2023.

Endostar (recombinant human endostatin injection) was included in the NRDL in 2017 through the national medical insurance pricing negotiation process, which was successfully renewed in 2019. Please see “Regulatory Overview – National Medical Insurance Program” for more details about such pricing negotiation process. Sales of Endostar accounted for 17.3%, 19.0% and 22.6% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Endostar increased from RMB669.7 million in 2017 to RMB1,136.5 million in 2019, representing a CAGR of 30.3%, while our sales volume of Endostar increased from approximately 1.0 million pre-filled syringes in 2017 to approximately 2.1 million pre-filled syringes in 2019, representing at a CAGR of 44.9%.

In terms of sales revenue, the market for targeted therapy drugs for NSCLC in China grew at a CAGR of 40.8% from 2015 to 2019, reaching RMB20.8 billion in 2019. Recombinant human endostatin was the seventh best-selling category of targeted therapy drug for NSCLC in terms of sales revenue in 2019, with a market share of 5.9%, according to Frost & Sullivan.

Endostar has received the following major awards and recognitions:

Awards and recognitions	Grantor	Year
Second Prize of the State Technological Innovation Award (國家技術發明二等獎)	State Council	2008
China Patents Gold Medal (中國專利金獎)	State Intellectual Property Office of the PRC (中華人民共和國國家知識產權局) World Intellectual Property Organization (世界知識產權組織)	2008



## BUSINESS

Awards and recognitions	Grantor	Year
National Major Scientific and Technological Special Project for Significant New Drugs Development during the 11th Five-year Plan Period (「十一五」國家重大新藥創制科技重大專項)	Implementation Management Office of Major Scientific and Technological Special Project for Significant New Drugs Development (重大新藥創制科技重大專項實施管理辦公室)	2010
National Key New Products (國家重點新產品)	Ministry of Science and Technology of the PRC (中華人民共和國科學技術部); Ministry of Ecology and Environment of the PRC (中華人民共和國生態環境部), formerly known as Ministry of Environmental Protection of the PRC (中華人民共和國環境保護部); MOFCOM; SAMR	2010

We are conducting various research and development efforts to maximize the commercial potential of Endostar. For example, we are currently developing PEG-ENDO, which is intended to enhance the pharmacokinetic properties of Endostar. Please see “– Our Product Pipeline” for more details.

*Jepaso (Nedaplatin) 捷佰舒® (奈達鉑)*

*First-to-market generic pharmaceutical, included in the NRDL*

Jepaso (nedaplatin for injection), our first-to-market generic pharmaceutical, is primarily used for the treatment of solid tumors such as head and neck neoplasms, small cell lung cancer, NSCLC, esophagus cancer and ovarian cancer. It is the first nedaplatin pharmaceutical product approved for sale in China, according to Frost & Sullivan. After nedaplatin enters into a cell, it releases aglycone of glycolate and inhibits the replication of DNA and thereby prevents the growth of tumor cells. As a second-generation platinum-based drug, nedaplatin is more soluble in water and appears to be less toxic to kidney and the digestive system compared with cisplatin, the first-generation platinum-based drug, and therefore more suitable for elderly patients as well as patients with renal insufficiency. According to various independent clinical studies, nedaplatin does not have full cross resistance against other platinum-based chemotherapy drugs and can be the preferred platinum-based chemotherapy drug for the treatment of esophagus cancer and head and neck neoplasms. According to a 2015 independent clinical research, nedaplatin-based chemotherapy significantly prolongs overall survival in patients with squamous cell lung cancer and is likely to be the new-generation standard treatment for advanced or recurrent NSCLC. The originator product of Jepaso was developed by Shionogi and was launched in Japan in 1995.

## BUSINESS

Attributable to its effectiveness in the treatment of esophagus cancer and mild adverse reactions, nedaplatin has gained wide recognition among healthcare professionals in China, and has been listed as a recommended first-line chemotherapy or palliative chemotherapy for esophagus cancer in various clinical practice guidelines, including, among others, the “Clinical Pathways for Esophagus Cancer Chemotherapy (2016)” (《食管癌治療臨床路徑 (2016版)》) issued by NHC, the “Standardized Esophagus Cancer Diagnosis and Treatment Guidelines (the Second Edition)” (《食管癌規範化診療指南 (第二版)》) published by China Union Medical University Press (中國協和醫科大學出版社) and the “China Esophagus Cancer Radiotherapy Guidelines (2019)” (《中國食管癌放射治療指南 (2019版)》) issued by CACA. Nedaplatin has also been recommended as a first-line therapy for advanced squamous cell lung cancer by the “Clinical Pathways for NSCLC Chemotherapy (2016)” (《非小細胞肺癌治療臨床路徑 (2016版)》) issued by NHC and the “Primary Lung Cancer Diagnosis and Treatment Guidelines (2019)” (《原發性肺癌診療指南 (2019版)》) issued by CSCO. In addition, Jepaso has been included in the “Consensus among Experts on Metastatic Nasopharynx Cancer (2018)” (《轉移性鼻咽癌專家共識 (2018版)》) issued by CACA as a treatment option for nasopharynx cancer.

As of the Latest Practicable Date, we held one invention patent on the refining method of the API of Jepaso in the PRC, which was valid until 2027.

Nedaplatin has been included in the NRDL since 2009. Sales of Jepaso accounted for 3.4%, 3.6% and 3.4% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Jepaso increased from RMB132.9 million in 2017 to RMB173.1 million in 2019, representing a CAGR of 14.1%, while our sales volume of Jepaso increased from approximately 2.0 million vials in 2017 to approximately 3.5 million vials in 2019, representing at a CAGR of 32.3%.

According to Frost & Sullivan, in terms of sales revenue, the platinum-based drug market in China grew at a CAGR of 9.9% from 2015 to 2019, while the nedaplatin drug market in China, being its third largest segment, grew at a CAGR of 0.4% during the same period, reaching RMB558.2 million in 2019. We were the first largest manufacturer in the nedaplatin drug market in China in terms of sales revenue in 2019, with a market share of 33.7%, according to Frost & Sullivan.

Jepaso has received the following major awards and recognitions:

Awards and recognitions	Grantor	Year
High and New Technology Product of Jiangsu (江蘇省高新技術產品)	Department of Science and Technology of Jiangsu Province (江蘇省科技廳)	2014
Famous Brand Product of Jiangsu (江蘇省名牌產品)	Jiangsu Promotion Commission for Famous Brand Strategy (江蘇省名牌戰略推進委員會)	2014

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## BUSINESS

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*Jiebaili (Pemetrexed Disodium) 捷佰立® (培美曲塞二鈉)*

*Included in the NRDL*

Jiebaili (pemetrexed disodium for injection), our generic drug, is a folate analog metabolic inhibitor that disrupts folate-dependent metabolic processes essential for cell replication and thereby prevents the growth of tumor cells. Jiebaili can be either used alone or in combination with other chemotherapy drugs and/or targeted drugs. The originator product of Jiebaili was developed by Eli Lilly and was launched in the United States in 2004.

Pemetrexed disodium has been included in various clinical practice guidelines as a full-line therapy for non-squamous NSCLC and a first-line therapy for pleural mesothelioma, including, among others, the “Primary Lung Cancer Diagnosis and Treatment Guidelines (2019)” (《原發性肺癌診療指南(2019版)》) and the “Consensus among Chinese Experts on Anti-angiogenic Drug for Treatment of Advanced NSCLC (2019)” (《晚期非小細胞肺癌抗血管生成藥物治療中國專家共識(2019版)》) issued by CSCO, the “Clinical Practice Guidelines in Oncology – NSCLC (2019, the Fifth Version)” (《臨床實踐指南之非小細胞肺癌(2019年第五版)》) and the “Clinical Practice Guidelines in Oncology – Malignant Pleural Mesothelioma (2019, the Second Version)” (《臨床實踐指南之惡性胸膜間皮瘤(2019年第二版)》) issued by the National Comprehensive Cancer Network, a not-for-profit alliance of leading cancer centers in the United States. Pemetrexed disodium has also been included in the “Clinical Practice Guidelines in Oncology – Cervical Cancer (2019, the Fourth Version)” (《臨床實踐指南之宮頸癌(2019年第四版)》) issued by the National Comprehensive Cancer Network.

As of the Latest Practicable Date, we held one invention patent on the formulation of Jiebaili in the PRC, which was valid until 2036.

Pemetrexed has been included in the NRDL since 2017. Sales of Jiebaili accounted for 2.2%, 3.2% and 2.5% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Jiebaili increased from RMB85.7 million in 2017 to RMB127.0 million in 2019, representing a CAGR of 21.7%, while our sales volume of Jiebaili increased from approximately 72,700 vials in 2017 to approximately 150,500 vials in 2019, representing at a CAGR of 43.9%.

According to Frost & Sullivan, in terms of sales revenue, the pemetrexed drug market in China grew at a CAGR of 9.5% from 2015 to 2019, reaching RMB3.4 billion in 2019. We were the sixth largest manufacturer in the pemetrexed drug market in China in terms of sales revenue in 2019, with a market share of 4.0%, according to Frost & Sullivan.

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## BUSINESS

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*Sinofuan (5-Fluorouracil) 中人氟安® (5-氟尿嘧啶)*

*New formulation drug, the only domestic antineoplastic sustained-release implant approved for sale in China*

Sinofuan (5-fluorouracil implants), our new formulation drug, is the only domestic antineoplastic sustained-release implant approved for sale in China, according to Frost & Sullivan. 5-Fluorouracil is primarily used for treatment of digestive system tumors, including esophagus cancer, colorectal cancer and gastric cancer. As a nucleoside metabolic inhibitor, 5-fluorouracil works by inhibiting the synthesis of DNA and RNA and thereby preventing the growth of tumor cells. Sustained-release implant, as a novel dosage form used in the treatment of digestive system tumors, which significantly enhances the local concentration of 5-fluorouracil shortly after administration and provides constant release over an extended period, while minimizing systemic toxicity and side effects.

As a recommended intraoperative chemotherapy drug for colorectal cancer, 5-fluorouracil has been included in the “Consensus among Chinese Experts on Drugs Used in Abdominal Cavity for Prevention and Treatment of Peritoneal Metastasis of Colorectal Cancer (2019)” (《結直腸癌腹膜轉移預防和治療腹腔用藥中國專家共識(2019版)》) and the “Consensus among Experts on NOSES for Colorectal Neoplasm (2019)” (《結直腸腫瘤經自然腔道取標本手術專家共識(2019版)》) issued by the Chinese Medical Doctor Association (中國醫師協會). In addition, 5-fluorouracil has been included in the “Interpretation of Clinical Pathways Therapy Drugs – Oncology Disease Volume (2015)” (《臨床路徑治療藥物釋義 – 腫瘤疾病分冊(2015年)》) published by China Union Medical University Press as a recommended intraoperative chemotherapy drug for gastric cancer, colorectal cancer and liver cancer.

Sales of Sinofuan accounted for 3.0%, 2.6% and 2.5% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Sinofuan increased from RMB116.6 million in 2017 to RMB128.3 million in 2019, representing a CAGR of 4.9%, while our sales volume of Sinofuan increased from approximately 369,100 vials in 2017 to approximately 374,000 vials in 2019, representing at a CAGR of 0.7%.

According to Frost & Sullivan, in terms of sales revenue, the intraoperative chemotherapy drug for digestive system cancer market in China grew at a CAGR of 29.9% from 2015 to 2019, reaching RMB2.1 billion in 2019. Sinofuan accounted for 6.6% of the intraoperative chemotherapy drug for digestive system cancer market in China in terms of sales revenue in 2019, according to Frost & Sullivan.

### ***Central Nervous System Products***

Our central nervous system product portfolio currently comprises three products, including one of our major products, Bicun. For the years ended December 31, 2017, 2018 and 2019, our sales of central nervous system products were RMB1,276.1 million, RMB1,202.0 million and RMB936.9 million, respectively, accounting for 33.3%, 27.9% and 19.5% of our revenue from sales of pharmaceutical products for the same periods, respectively.

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## BUSINESS

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According to Frost & Sullivan, central nervous system diseases were the 4th largest therapeutic area in China in terms of sales revenue of pharmaceuticals in 2019, accounting for 12.5% of the overall pharmaceutical market in the same year. In terms of sales revenue, the central nervous system pharmaceutical market in China grew at a CAGR of 9.1% from RMB144.0 billion in 2015 to RMB204.3 billion in 2019. The central nervous system pharmaceutical market in China is expected to grow further at a CAGR of 4.6% from 2020 to 2024, reaching RMB250.9 billion in 2024. The central nervous system pharmaceutical market in China is expected to continue its growth leveraging key drivers including an increasing number of patients as well as their increasing disposable income, launch of new products and indication expansion of existing products, according to Frost & Sullivan.

*Bicun (Edaravone) 必存® (依達拉奉)*

*First-to-market generic pharmaceutical, the second edaravone injection approved for sale in worldwide*

Bicun (edaravone injection), our first-to-market generic pharmaceutical for the treatment of stroke, is the first edaravone injection approved for sale in China and the second edaravone injection approved for sale worldwide, according to Frost & Sullivan. Edaravone is a synthetic free radical scavenger used to improve the neurological symptoms and dysfunction of activities of daily living caused by acute cerebral infarction. Edaravone protects the brain by eliminating excessive free radicals, which are highly reactive molecules occurring in the human body as a result of cerebral infarction that could result in damage to cerebral cells. Meanwhile, it inhibits the decrease of regional cerebral blood flow in cerebral infarction. Edaravone is a neuroprotective agent that has been proven as effective and safe in improving the functional outcomes of patients with acute cerebral infarction, according to multiple randomized, double-blind placebo controlled clinical trials both in China and abroad. The originator product of Bicun was developed by Mitsubishi Tanabe Pharma Corporation and was launched in Japan in 2001.

Edaravone has been recommended by a number of clinical practice guidelines and consensus in China and abroad for treatment of stroke, such as the “Acute Ischemic Stroke Diagnosis and Treatment Guidelines” (《中國急性缺血性腦卒中診治指南》) issued by Chinese Medical Association in 2010, 2015 and 2018, the “Guidelines for the Early Management of Patients with Acute Ischemic Stroke” issued by American Heart Association and American Stroke Association in 2007 and 2013, the “Cerebral Hemorrhage Diagnosis and Treatment Guidelines” (《腦出血診治指南》) issued by Chinese Medical Association in 2015, the “Clinical Pathways for Cerebral Infarction (2016)” (《腦梗死臨床路徑(2016版)》), the “Clinical Pathways for Cerebral Hemorrhage (2016)” (《腦出血臨床路徑(2016版)》) and the “Acute-Stage Ischemic Stroke Diagnosis and Treatment Guidelines (2017)” (《缺血性腦卒中急性期診療指導規範(2017版)》) issued by the NHC, the “Japanese Guidelines for the Management of Stroke 2015 (2017 Revised)” issued by the Japan Stroke Society and the “China Cerebrovascular Disease Clinical Management Guidelines (2019)” (《中國腦血管病臨床管理指南(2019版)》) issued by the China Stroke Association.



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## BUSINESS

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As of the Latest Practicable Date, we held or jointly-held two invention patents on the new application of the API of Bicun in the PRC, with expiry dates ranging from 2025 to 2031.

Sales of Bicun accounted for 32.2%, 26.6% and 18.6% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Bicun was RMB1,244.2 million, RMB1,198.6 million and RMB936.9 million in 2017, 2018 and 2019, respectively, while our sales volume of Bicun was approximately 38.8 million ampoules, approximately 38.4 million ampoules and approximately 29.1 million ampoules in 2017, 2018 and 2019, respectively.

According to Frost & Sullivan, in terms of sales revenue in 2019, the size of the edaravone drug market in China, being the third largest segment of the neuroprotective agent market in China, amounted to RMB2.9 billion. Bicun was the best-selling edaravone drug in terms of sales revenue in 2019, with a market share of 36.8%, according to Frost & Sullivan. Bicun was awarded the “High and New Technology Product of Jiangsu Province (江蘇省高新技術產品)” by Department of Science and Technology of Jiangsu Province (江蘇省科學技術廳) in 2013.

### ***Autoimmune Products***

Our autoimmune product portfolio currently comprises four products, including two of our major products, Iremod and Yingtaiqing. For the years ended December 31, 2017, 2018 and 2019, our sales of autoimmune products were RMB423.2 million, RMB537.8 million and RMB813.8 million, respectively, accounting for 11.0%, 12.5% and 17.0% of our revenue from sales of pharmaceutical products for the same periods, respectively.

According to Frost & Sullivan, autoimmune diseases were one of the fastest growing therapeutic areas in China in terms of sales revenue of pharmaceuticals in 2019. In terms of sales revenue, the autoimmune pharmaceutical market grew at a CAGR of 13.4% from RMB9.8 billion in 2015 to RMB16.2 billion in 2019, and is expected to grow further at a CAGR of 27.2% from 2020 to 2024, reaching RMB53.2 billion in 2024. An increasing number of patients, as well as their increasing disposable income and health awareness, the inclusion of additional pharmaceuticals into the NRDL, the improvement of diagnosis and treatment level, and the development of innovative therapies and pharmaceuticals are expected to continue to drive the future growth of the autoimmune pharmaceutical market in China, according to Frost & Sullivan.

*Iremod (Iguratimod) 艾得辛® (艾拉莫德)*

*Innovative pharmaceutical, included in the NRDL, the only iguratimod drug approved for sale in China*

Iremod (iguratimod tablets), our category I innovative chemical drug for the treatment of active rheumatoid arthritis, is the only iguratimod pharmaceutical product approved for sale in China and the first iguratimod pharmaceutical product approved for sale in the world, according to Frost & Sullivan. Iguratimod is a type of conventional synthetic DMARD that slows down the progression of active rheumatoid arthritis by inhibiting the generation of

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## BUSINESS

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inflammatory cytokines. According to our phase III clinical trials that commenced in 2008, Iremod administered as a monotherapy in rheumatoid arthritis patients has shown ACR20 (meaning at least a 20% improvement in rheumatoid arthritis symptoms) response rate of 63.8% at week 24. According to a randomized, double-blind, parallel-controlled clinical trial conducted in Japan in 2013, iguratimod administered in combination with other drugs in rheumatoid arthritis patients has shown an ACR20 response rate of 71.3% at week 52. According to our phase IV post-marketing clinical trials that commenced in 2012, Iremod administered in combination with other drugs in rheumatoid arthritis patients has demonstrated an ACR20 response rate of 71.9% at week 24. As an orally-administered chemical drug, Iremod is easier to administer and more affordable than biologic DMARDs that are costly and require intravenous or subcutaneous injections, offering the potential to significantly improve the symptoms of active rheumatoid arthritis patients.

Iguratimod has been recommended as the primary therapy drug for the treatment of active rheumatoid arthritis by a number of clinical practice guidelines. In particular, it has been recommended by the “Guidelines for the Diagnosis and Treatment of Rheumatoid Arthritis” issued by the Ministry of Health, Labor and Welfare of Japan in 2014, the “Rheumatoid Arthritis Treatment Guidelines” (《類風濕關節炎治療指南》) issued by the Asia Pacific League of Associations for Rheumatology in 2015 and 2018, the “Clinical Pathways for Rheumatoid Arthritis” (《類風濕性關節炎臨床路徑》) issued by the NHC in 2016 and the “China Rheumatoid Arthritis Diagnosis and Treatment Guidelines” (《中國類風濕關節炎診療指南》) issued by the Chinese Medical Association in 2018.

As of the Latest Practicable Date, we jointly-held one invention patent on the formulation of Iremod in the PRC, which was valid until 2023. As of the Latest Practicable Date, we also jointly-held four invention patents on the crystalline form of the API of Iremod in the PRC, which were valid until 2025. In addition, as of the Latest Practicable Date, we held one invention patent on the impurity of Iremod and the application of such impurity in the PRC, which was valid until 2029.

Iguratimod has been included in the NRDL since 2017. Sales of Iremod accounted for 4.1%, 6.5% and 10.3% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Iremod increased from RMB159.0 million in 2017 to RMB520.2 million in 2019, representing a CAGR of 80.9%, while our sales volume of Iremod increased from approximately 14.7 million tablets in 2017 to approximately 47.7 million tablets in 2019, representing at a CAGR of 80.1%.

According to Frost & Sullivan, in terms of sales revenue, the conventional synthetic DMARD market in China grew at a CAGR of 12.4% from 2015 to 2019, reaching RMB3.1 billion in 2019. Iguratimod was the third best-selling category of conventional synthetic DMARD in terms of sales revenue in 2019, with a market share of 18.4%, according to Frost & Sullivan.

## BUSINESS

Iremod has received the following major awards and recognitions:

Awards and recognitions	Grantor	Year
National Major Scientific and Technological Special Project for Significant New Drugs Development during the 12th Five-year Plan Period (「十二五」國家重大新藥創制科技專項)	Implementation Management Office of Major Scientific and Technological Special Project for Significant New Drugs Development (重大新藥創制科技重大專項實施管理辦公室)	2012
National Torch Program Project (國家火炬計劃項目)	Ministry of Science and Technology of the PRC (中華人民共和國科學技術部)	2013
First Class Award of Science and Technology Progress Prizes of Hainan Province (海南省科學技術進步一等獎)	People’s Government of Hainan Province (海南省人民政府)	2014

*Yingtaiqing (Diclofenac Sodium) 英太青® (雙氯芬酸鈉)*

*Included in the NRDL*

Yingtaiqing (diclofenac sodium sustained-release capsules and gel) is a non-steroidal anti-inflammatory analgesic drug for the treatment and relief of pain caused by rheumatoid arthritis and osteoarthritis, soft tissue rheumatic pains and various mild and moderate body aches. It eases pain and reduces inflammation by blocking the effect of cyclooxygenase enzymes, which produce prostaglandins in the body that cause pain and inflammation. With its unique sustained-release pellet technology, it becomes effective within one hour and lasts up to 12 hours, providing fast and effective pain relief.

Non-steroidal anti-inflammatory drugs have been recommended as the primary therapy for osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in the “Osteoarthritis Diagnosis and Treatment Guidelines” (《骨關節炎診療指南》) issued by Chinese Medical Association in 2018, and the “Clinical Pathways for Osteoarthritis” (《骨關節炎臨床路徑》), the “Clinical Pathways for Rheumatoid Arthritis” (《類風濕性關節炎臨床路徑》) and the “Clinical Pathways for Ankylosing Spondylitis” (《強直性脊柱炎臨床路徑》) issued by the NHC in 2016.

We currently sell and/or promote Yingtaiqing-branded sustained-release capsules and gel in China. During the Track Record Period, a substantial portion of the Yingtaiqing-branded sustained-release capsules that we sold and/or promoted were produced by a third-party manufacturer, CPU Pharma pursuant to exclusive agreements with CPU Pharma. Please see “– Sales, Marketing and Distribution-Distribution and Promotion of Third-party Pharmaceutical Products” for more details. We have also obtained the NMPA approval to produce and sell

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## BUSINESS

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diclofenac sodium sustained-release capsules and gel in 2002 and 2005, respectively. However, pursuant to our non-competition undertaking to CPU Pharma which is in line with our general practice for other third-party pharmaceutical products, we agreed not to produce diclofenac sodium sustained-release capsules unless necessary to meet the requirements of PRC laws and regulations.

Diclofenac sodium sustained-release capsules have been included in the NRDL since 2004. Sales of Yingtaiqing accounted for 6.8%, 5.4% and 5.8% of our total revenue in 2017, 2018 and 2019, respectively, of which sales of Yingtaiqing-branded capsules contributed to a substantial portion. Our revenue derived from sales of Yingtaiqing increased from RMB261.5 million in 2017 to RMB289.9 million in 2019, representing a CAGR of 5.3%. Our sales volume of Yingtaiqing-branded capsules increased from approximately 424.7 million pills in 2017 to approximately 458.6 million pills in 2019, representing a CAGR of 3.9%; and our sales volume of Yingtaiqing-branded gel increased from 871,237 tubes in 2017 to 945,204 tubes in 2019, representing at a CAGR of 4.2%.

According to Frost & Sullivan, in terms of sales revenue, the non-steroidal anti-inflammatory drug market in China grew at a CAGR of 13.6% from 2015 to 2019, while the mono-ingredient diclofenac sodium drug market in China grew at a CAGR of 11.0% during the same period, reaching RMB1.7 billion in 2019. We ranked the first in mono-ingredient diclofenac sodium drug market in China in terms of sales revenue in 2019, with a market share of 18.1%, according to Frost & Sullivan.

### ***Cardiovascular Products***

Our cardiovascular product portfolio currently comprises three products, including one of our major products, Softan. We also market and/or sell OLMETEC PLUS (olmesartan medoxomil and hydrochlorothiazide tablets) developed and manufactured by Daiichi Sankyo. Angiotensin II receptor blocker is the most prescribed category of anti-hypertensive pharmaceuticals worldwide according to Frost & Sullivan, while OLMETEC PLUS is a new-generation fixed-dose combination of an angiotensin II receptor blocker, olmesartan medoxomil, and a thiazide diuretic, hydrochlorothiazide, and an exclusive product in the PRC pharmaceutical market.

For the years ended December 31, 2017, 2018 and 2019, our sales of cardiovascular products were RMB243.4 million, RMB353.1 million and RMB445.5million, respectively, accounting for 6.3%, 8.2% and 9.3% of our revenue from sales of pharmaceutical products for the same periods, respectively.

According to Frost & Sullivan, sales revenue of cardiovascular pharmaceuticals accounted for 13.0% of the overall pharmaceutical market in 2019. In terms of sales revenue, the cardiovascular pharmaceutical market in China grew at a CAGR of 7.5% from RMB158.8 billion in 2015 to RMB212.2 billion in 2019, and is expected to grow further at a CAGR of 3.3% from RMB217.5 billion in 2020 to RMB247.7 billion in 2024, according to Frost & Sullivan.

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## BUSINESS

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*Softan (Rosuvastatin Calcium) 舒夫坦® (瑞舒伐他汀钙)*

*Included in the NRDL, passed the consistency evaluation*

Softan (rosuvastatin calcium tablets), our generic pharmaceutical, is a selective inhibitor of HMG-CoA reductase and a cholesterol lowering statin. Softan lowers the cholesterol level by increasing the number of receptors on liver cells to augment the uptake and catabolism of LDL while inhibiting the synthesis of VLDL in the liver, and thereby reducing both LDL and VLDL levels. Moreover, it can be used by patients to reduce the risk of cardiovascular diseases or the need for medical procedures to open blocked heart vessels.

It is used to treat patients with primary hypercholesterolemia (type IIa) or mixed dyslipidemia (type IIb) whose blood cholesterol levels cannot be properly controlled through dieting or other non-medication therapies. It can also be used as an adjunctive therapy for patients with homozygous familial hypercholesterolemia. Our Phase III clinical trial for Softan has demonstrated that it has the same quality and effectiveness as the originator product and is more effective in lowering cholesterol than other commonly-used statins. The originator product of Softan was developed by AstraZeneca and was launched in China in 2004.

Rosuvastatin calcium has been included in a number of clinical practice guidelines in China as a recommended therapy drug for dyslipidemia, including the “China Adults Dyslipidemia Prevention and Treatment Guidelines (2016 Revised)” (《中國成人血脂異常防治指南 (2016修訂版)》) issued by a joint commission of multi-disciplinary experts and the “Guidelines for Rational Drug Use for Dyslipidemia (2019)” (《血脂異常合理用藥指南(2019版)》) issued by the NHC. Meanwhile, it has been recommended by various clinical practice guidelines in the United States, Canada and the European Union as the first-line treatment for lowering blood cholesterol, such as the “Canadian Guidelines for the Diagnosis and Treatment of Dyslipidemia and Prevention of Cardiovascular Disease in the Adult” issued by Canadian Cardiovascular Society in 2009, and the “Guidelines on the Management of Blood Cholesterol” issued by the American College of Cardiology and the American Heart Association in 2013 and 2018.

Rosuvastatin has been included in the NRDL since 2009. Sales of Softan accounted for 4.6%, 6.2% and 6.6% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Softan increased from RMB179.2 million in 2017 to RMB334.9 million in 2019, representing a CAGR of 36.7%, while our sales volume of Softan increased from approximately 77.8 million tablets in 2017 to approximately 176.9 million tablets in 2019, representing a CAGR of 50.8%.

According to Frost & Sullivan, in terms of sales revenue, the rosuvastatin market in China grew at a CAGR of 12.7% from 2015 to 2019, reaching RMB6.8 billion in 2019. We were the fifth largest player in the rosuvastatin drug market in China in terms of sales revenue in 2019, with a market share of 5.4%, according to Frost & Sullivan.

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## BUSINESS

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### *Anti-Infective Products*

Our anti-infective product portfolio currently comprises 15 products, including two of our major products, Newanti and ZAILIN. Our anti-infective product portfolio also includes our ZAILIKE-branded arbidol dispersible tablets, broad-spectrum anti-viral for treatment of influenza. Arbidol has been included in the NRDL in 2019. Arbidol is a hemagglutinin fusion inhibitor and was proven to be effective against viruses resistant to oseltamivir, a neuraminidase inhibitor. Arbidol is recommended by the NHC in its “Guidelines for the Diagnosis and Treatment of Influenza (2019 Edition)” (《流行性感冒診療方案(2019年版)》) and “Guidelines for the Diagnosis and Treatment of COVID-19 (Sixth/Seventh Editions for Trial Implementation)” (《新冠肺炎診療方案(試行第六版、第七版)》).

For the years ended December 31, 2017, 2018 and 2019, our sales of anti-infective products were RMB564.7 million, RMB579.5 million and RMB635.7 million, respectively, accounting for 14.7%, 13.4% and 13.2% of our revenue from sales of pharmaceutical products for the same periods, respectively.

According to Frost & Sullivan, sales revenue of anti-infective pharmaceuticals accounted for 13.8% of the overall pharmaceutical market in 2019. In terms of sales revenue, the anti-infective market in China grew at a CAGR of 3.6% from RMB195.8 billion in 2015 to RMB225.5 billion in 2019, and is expected to grow further at a CAGR of 3.2% from RMB230.0 billion in 2020 to RMB260.7 billion in 2024.

*Newanti (Biapenem) 安信® (比阿培南)*

*First-to-market generic pharmaceutical, included in the NRDL*

Newanti (biapenem for injection), our first-to-market generic pharmaceutical, is a new-generation carbapenem antibiotic for injection and the first biapenem pharmaceutical product approved for sale in China, according to Frost & Sullivan. Newanti is used for the treatment of moderate to severe bacterial infections, such as septicemia, pneumonia and lung abscess caused by sensitive bacteria, secondary infections caused by chronic respiratory disease, refractory cystitis, pyelonephritis, peritonitis and annexitis. It is primarily used to treat critically-ill, hospitalized patients suffering from serious infections, and is predominantly consumed in hospitals’ intensive care units and respiratory and hematology departments. According to a 2012 clinical research jointly conducted by the Guangzhou Institute of Respiratory Diseases (廣州呼吸疾病研究所) and us, Newanti has stronger in-vitro antibacterial activity for multiple strains of common bacteria, compared to meropenem and imipenem, its competing products. According to independent clinical trial reports issued in 2012, biapenem is more effective in treating moderate to severe lower respiratory infection with lower incidence of adverse events in central nervous system, as compared to imipenem/cilastatin. According to independent clinical trial reports issued in 2016, biapenem indicates similar efficacy and safety profile in treating lower respiratory infection, complicated urinary tract infection and complex intra-abdominal infection, as compared to meropenem and imipenem/cilastatin. The originator product of Newanti was developed by Meiji Seika and was launched in Japan in 2001.



## BUSINESS

Biapenem has been recommended as a primary carbapenem antibiotic in a number of clinical practice guidelines, including the “National Guidelines for Antimicrobial Therapy” (《國家抗微生物治療指南》) issued by NHC in 2012, the “Guidelines for Clinical Application of Antibacterial Drugs (2015)” (《抗菌藥物臨床應用指導原則2015年版》) issued by NHC, the “China Adults Community-Acquired Pneumonia Diagnosis and Treatment Guidelines (2016)” (《中國成人社區獲得性肺炎診斷和治療指南(2016版)》) and the “China Adults Hospital-Acquired Pneumonia and Ventilator-Associated Pneumonia Diagnosis and Treatment Guidelines (2018)” (《中國成人醫院獲得性肺炎與呼吸機相關性肺炎診斷和治療指南(2018版)》), and the “Consensus among Experts on Diagnosis and Treatment for End-Stage Liver Disease with Infection (2018)” (《終末期肝病合併感染診治專家共識(2018版)》) issued by Chinese Medical Association. Moreover, biapenem has also been recommended by the “Guidelines for Treatment of Respiratory Tract Infection” issued by the Japanese Association for Infectious Diseases and Japanese Society of Chemotherapy in Japan in 2016.

As of the Latest Practicable Date, we held one invention patent on the impurity of Newanti and the application of such impurity in the PRC, which was valid until 2027. As of the Latest Practicable Date, we also held one invention patent on the preparation method of the API of Newanti in the PRC, which was valid until 2026.

Biapenem has been included in the NRDL since 2009. Sales of Newanti accounted for 6.6%, 5.7% and 5.6% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of Newanti increased from RMB257.1 million in 2017 to RMB283.9 million in 2019, representing a CAGR of 5.1%, while our sales volume of Newanti increased from approximately 2.4 million vials in 2017 to approximately 3.2 million vials in 2019, representing at a CAGR of 15.5%.

According to Frost & Sullivan, in terms of sales revenue, the carbapenem drug market in China grew at a CAGR of 6.6% from 2015 to 2019 in terms of sales revenue, while the biapenem drug market in China, being its third largest segment, grew at a CAGR of 2.1% during the same period, reaching RMB1.0 billion in 2019. Newanti ranked second in the biapenem drug market in China in terms of sales revenue in 2019, with a market share of 32.5%, according to Frost & Sullivan.

The research and development of Newanti was funded by the technology fund allocated by the Department of Science and Technology of Jiangsu Province (江蘇省科學技術廳) and the Department of Finance of Jiangsu Province (江蘇省財政廳) in 2009. Newanti was awarded the “High and New Technology Product of Jiangsu (江蘇省高新技術產品)” by the Department of Science and Technology of Jiangsu Province (江蘇省科學技術廳) in 2014.

*ZAILIN (Amoxicillin) 再林® (阿莫西林)*

*Included in the NRDL, certain dosage forms passed consistency evaluation*

ZAILIN is the brand name for our line of generic amoxicillin antibiotics in dosage forms including capsules, dispersible tablets and granules. Amoxicillin is a type of semi-synthetic penicillin  $\beta$ -lactam antibiotic used for the treatment of various bacterial infections, such as

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## BUSINESS

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upper respiratory infection of tympanitis, nasosinusitis, pharyngitis and amygdalitis, lower respiratory infection of acute bronchitis and pneumonia, urogenital infections and skin/soft tissue infections. Amoxicillin has been widely recommended in almost all the major clinical practice guidelines on the use of antibiotics.

As of the Latest Practicable Date, we held one invention patent on the formulation of ZAILIN in the PRC, which was valid until 2030.

Amoxicillin has been included in the NRDL since 2004. Sales of ZAILIN accounted for 4.9%, 4.2% and 4.0% of our total revenue in 2017, 2018 and 2019, respectively. Our revenue derived from sales of ZAILIN increased from RMB189.2 million in 2017 to RMB199.7 million in 2019, representing a CAGR of 2.7%. Our sales volume of ZAILIN-branded capsules increased from approximately 200.4 million pills in 2017 to approximately 220.0 million in 2019, representing at a CAGR of 4.8%; our sales volume of ZAILIN-branded granules decreased slightly from approximately 306.1 million packs in 2017 to approximately 302.4 million packs in 2019; and our sales volume of ZAILIN-branded tablets increased from approximately 64.4 million pills in 2017 to approximately 67.4 million pills in 2019, representing at a CAGR of 2.3%.

According to Frost & Sullivan, in terms of sales revenue, the mono-ingredient amoxicillin drug market in China grew at a CAGR of 1.2% from 2015 to 2019, reaching RMB3.0 billion in 2019. We were the fourth largest manufacturer in the mono-ingredient amoxicillin drug market in China in terms of sales revenue in 2019, with a market share of 7.1%, according to Frost & Sullivan.

ZAILIN granules were awarded the “High and New Technology Product of Hainan (海南省高新技術產品)” by the Department of Science and Technology of Hainan Province (海南省科學技術廳) in 2012.

### ***Other Products***

We currently sell and/or promote a number of other pharmaceutical products, such as our Biqi-branded diosmectite powder, our anti-diarrhea products, which have obtained EU GMP certification and are currently sold in both China and the Europe. We also sell a number of APIs, such as diosmectite. For the years ended December 31, 2017, 2018 and 2019, sales of other products were RMB324.6 million, RMB356.9 million and RMB399.6 million, respectively, accounting for 8.5%, 8.3% and 8.3% of our revenue from sales of pharmaceutical products for the same periods, respectively.

### **KN035 (Envafolimab)**

In March 2020, we entered into collaboration agreements with Jiangsu Alphamab and 3D Medicines Beijing, which have granted us the exclusive right to promote KN035 for all oncology indications in China. Please see “– Our Collaboration Arrangements.” KN035 is potentially the first subcutaneously injectable anti-PD-L1 monoclonal antibody worldwide and

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## BUSINESS

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is expected to be the first anti-PD-L1 monoclonal antibody for MSI-H solid tumors or BTC approved for sale in the PRC, according to Frost & Sullivan. Our collaboration partners are currently conducting phase II clinical trials of KN035 for dMMR/MSI-H colorectal carcinoma and other advanced solid tumors and phase III clinical trials for advanced BTC in mainland China as well as phase I clinical trials in the United States and Japan. KN035 is expected to submit NDA in the second half of 2020 and launch in the PRC market in 2021.

As a subcutaneously injectable anti-PD-L1 monoclonal antibody, we believe that KN035 may reach a broader patient group and could be a more valuable option for patients with advanced solid tumors who are not suitable for intravenous infusion. With its unique molecule design and approximately half of the clinical dosage of other anti-PD-L1 monoclonal antibodies launched in the market, KN035 has shown similar efficacy and safety profile. In particular, according to the clinical data released at the 2020 annual meeting of the American Society of Clinical Oncology, KN035 has demonstrated an ORR of 34.0% for dMMR/MSI-H advanced solid tumors and an ORR of 54.2% in the colorectal cancer patients who had prior therapy with fluoropyrimidine and oxaliplatin or irinotecan. In combination with FOLFOX, as a first-line therapy for advanced gastric cancer and gastroesophageal borderline tumor, the ORR is 60% and the median PFS is 6.8 months.

In addition to dMMR/MSI-H solid tumors and BTC, Jiangsu Alphamab and 3D Medicines Beijing are currently exploring opportunities to extend the indications of KN035 to other tumors. We plan to collaborate with Jiangsu Alphamab and 3D Medicines Beijing to develop a number of combination therapies with KN035 for the treatment of solid tumors, in order to further enhance the competitiveness of KN035.

According to Frost & Sullivan, the sales revenue of the PD-1/PD-L1 mAb market in China is expected to grow rapidly at a CAGR of 56.1% from RMB13.8 billion in 2020 to RMB81.9 billion in 2024. We expect KN035 has vast market potential and its launch will continue to allow us to capture market share in the oncology pharmaceutical market in China.

### **Our Product Pipeline**

We have a proven track record of successfully developing and commercializing innovative and first-to-market generic pharmaceuticals. We employ a market oriented approach to R&D, addressing significant unmet medical needs, and focus our R&D efforts on innovative and high entry-barrier generic pharmaceuticals in oncology, central nervous system disease and autoimmune disease therapeutic areas. We have, through our in-house R&D team and R&D collaborations, developed and launched a variety of market-leading innovative and first-to-market generic pharmaceuticals in China. As one of the few pharmaceutical companies in China that have independently completed the full-cycle research and development of category I small molecule drugs and therapeutic biologic products, we have accumulated extensive R&D experience, which we leverage to collaborate with our domestic and international R&D partners to bring technologically-advanced drugs to the PRC market.

## BUSINESS

### Innovative Product Pipeline

As of the Latest Practicable Date, we had a pipeline of nearly 50 innovative product candidates in different stages of development. The following table sets forth selected information of our key innovative product candidates:

Therapeutic area	Product candidate	Classification	Target/mechanism	Intended indication(s)	Collaboration with R&D partner(s)	Status					
						Pre-clinical	IND	Phase I	Phase II	Phase III	NDA/IDL
Oncology	Sevacizumab (Humanized anti-VEGF monoclonal antibody for injection) (賽伐珠單抗/注射用人源化抗VEGF單克隆抗體)	Biologics	VEGF	Ovarian cancer	Collaboration with Apexigen	Phase I clinical trials					
	PEG-ENDO (Pegylated recombinant human endostatin for injection)	Biologics	Angiogenesis pathway	Advanced NSCLC	N/A	Phase Ib clinical trials					
	CD19 CAR T-cell therapy (Indication 1)	Biologics – cell therapy	CD19	r/r CD19 positive non-Hodgkin's lymphoma	Collaboration with Immunochina	IND approval obtained <sup>(1)</sup>					
	CD19 CAR T-cell therapy (Indication 2)	Biologics – cell therapy	CD19	r/r CD19 positive B-cell acute lymphoblastic leukemia	Collaboration with Immunochina	IND approval obtained <sup>(1)</sup>					
	BCMA CAR T-cell therapy	Biologics – cell therapy	BCMA	r/r multiple myeloma	Collaboration with PREGENE	IND approval obtained <sup>(1)</sup>					
	SIM - 201	Small molecule drug	NTRK	Solid tumors	N/A	IND application submitted					
	SIM - 325	Biologics – cell therapy	Undisclosed	Cervical cancer, head and neck cancer	Collaboration with TCRcure Beijing	Pre-clinical					
	Subcutaneous PD-L1 single domain antibody combination therapy – 1	Biologics	Undisclosed	Solid tumors	Collaboration with Jiangsu Alphamab and 3D Medicines Beijing	Pre-clinical					
	Subcutaneous PD-L1 single domain antibody combination therapy – 2	Biologics	Undisclosed	Solid tumors	Collaboration with Jiangsu Alphamab and 3D Medicines Beijing	Pre-clinical					
	SIM - 323	Biologics	Undisclosed	Solid tumors	Collaboration with GI Innovation	Pre-clinical					
	SIM - 235	Biologics	Undisclosed	Solid tumors	N/A	Pre-clinical					
	SIM - 237	Biologics	PD-L1 and IL15 receptor	Solid tumors	N/A	Pre-clinical					
	SIM - 200	Small molecule drug	EGFR	NSCLC	N/A	Pre-clinical					
	SIM - 236	Biologics	Undisclosed	Solid tumors	N/A	Pre-clinical					
	SIM - 203 - 1	Biologics	Undisclosed	Solid tumors	Collaboration with Merus	Pre-clinical					
	SIM - 203 - 2	Biologics	Undisclosed	Solid tumors	Collaboration with Merus	Pre-clinical					
	SIM - 203 - 3	Biologics	Undisclosed	Solid tumors	Collaboration with Merus	Pre-clinical					
Central nervous system	Edaravone and desborneol concentrated solution for injection (依达拉奉右莰醇注射用濃溶液)	Small molecule drug	Free radicals and inflammatory cytokines	Acute ischemic stroke	N/A	NDA filed					
	Y-2 sublingual tablets (Y-2舌下片)	Small molecule drug	Free radicals and inflammatory cytokines	Acute ischemic stroke	Collaboration with YenePharma	Phase I clinical trials					
	SIM-307	Small molecule drug	AQP4	Cerebral edema caused by stroke	Collaboration with Aeromics	Preparation for IND application					
	SIM-339	Small molecule drug – peptide therapeutics	Undisclosed	Cerebral infarction	Collaboration with Primary Peptides	Pre-clinical					
Autoimmune	Abatacept injection (阿巴西普注射液)	Biologics	CTLA4	Rheumatoid arthritis	Collaboration with BMS	IDL approval obtained					
	SIM-335	Small molecule drug	Multiple cytokines	Psoriasis	N/A	IND approval obtained					
	Iguratimod tablets (New indication) (艾拉莫德片/新適應症)	Small molecule drug	Inflammatory cytokines and immunoglobulins	Sjögren's syndrome	N/A	Preparation for IND application					
	SIM-295	Small molecule drug	URAT1	Gout with hyperuricemia	Collaboration with JW Pharmaceutical	Preparation for IND application					

Note:

- (1) Phase II clinical trials could be used as the pivotal trials for NDA submission.

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## BUSINESS

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Our oncology product candidates primarily focus on solid tumors and hematologic malignancies, including (i) monoclonal antibodies with a number of angiogenesis inhibitors, which will not only further solidify our market position in the relevant sectors, and also enable us to explore combination therapies with immune checkpoint inhibitors; (ii) small molecule drugs that target cancer driver genes; and (iii) cell therapy products which have the potential to offer novel and curative treatment to patients with hematologic malignancies. Our central nervous system product candidates aim to offer full-cycle medications for patients with stroke, from the relief and early treatment of mild to moderate acute stroke, maintenance treatment after patient discharge, and to the treatment of cerebral edema caused by severe stroke. Our autoimmune product candidates consist of both new drugs and existing drugs with new indications, targeting major indications that have significant unmet medical needs, including rheumatoid arthritis, Sjögren’s syndrome, psoriasis and gout.

Below is a description of certain of our key innovative product candidates:

### *Oncology Product Candidates*

1. Sevacizumab (Humanized anti-VEGF monoclonal antibody for injection) (賽伐珠單抗(注射用人源化抗VEGF單克隆抗體))

Sevacizumab is a new-generation recombinant humanized anti-VEGF monoclonal antibody intended for the treatment of ovarian cancer. This product candidate targets the pro-angiogenic function of VEGF and thereby inhibits the angiogenesis, growth and metastasis of tumors. In its pre-clinical studies, it has shown higher tumor suppression efficacy in multiple cancer models, compared to bevacizumab at the same dose. We are currently conducting phase I clinical trials for this product candidate in China and the preliminary results have shown a favorable safety profile and early efficacy signals. We expect to initiate phase II/III clinical trials in 2021.

According to Frost & Sullivan, ovarian cancer incidence in China grew at a CAGR of 1.8% from 50.2 thousand in 2015 to 53.9 thousand in 2019 and is expected to further grow further at a CAGR of 1.5% from 54.8 thousand in 2020 to 58.1 thousand in 2024. As of December 31, 2019, there were two targeted therapy drugs for ovarian cancer approved for sale in China, according to Frost & Sullivan. In addition, there were 11 targeted therapy drug candidates for ovarian cancer pending NDA approval or at clinical stages in China as of December 31, 2019, among which six are biologics, including our sevacizumab, and five are chemical drugs, according to Frost & Sullivan.

We are collaborating with Apexigen on the development and commercialization of this product candidate. Please see “– Our Collaboration Arrangements.”

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## BUSINESS

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### 2. PEG-ENDO (Pegylated recombinant human endostatin for injection)

PEG-ENDO is our innovative biologic drug candidate, which we have been developing in-house, as an improved version of Endostar, one of our major products. This product candidate enhances the pharmacokinetic properties of recombinant human endostatin by conjugation with a methoxy polyethylene glycol aldehyde, while retaining its biological activities. Pharmacodynamic studies in animal models have demonstrated that this product candidate can significantly enhance the effects of chemotherapy in multiple cancer models when used in combination with chemotherapy drugs. We are currently conducting phase Ib clinical trials for this product candidate in China and expect such clinical trials to be completed in 2021.

### 3. CD19 CAR T-cell Therapies

CD19 CAR T-cell therapies are innovative genetically modified cell therapies for the treatment of r/r CD19 positive B-cell non-Hodgkin’s lymphoma and r/r CD19 positive B-cell acute lymphoblastic leukemia. Chimeric antigen receptor T cells, or CAR T-cells, represent T cells that have been genetically engineered to express an artificial T-cell receptor and therefore become able to target a specific antigen. As a biomarker for B cells, CD19 is expressed at normal to high levels in a majority of B cell malignancies, including non-Hodgkin’s lymphoma and acute lymphoblastic leukemia. CD19 CAR T-cells specifically recognize and target CD19 and kill tumor cells. Investigator-initiated clinical trials for lymphoma have shown a 6-month ORR of 53% and the median PFS of nine months, which are comparable to Yescarta and Kymriah. We have obtained the IND approval for our CD19 CAR T-cell therapy candidates and plan to initiate phase I clinical trials in China in the second half of 2020. We expect to submit the NDA for our CD19 CAR T-cell therapy candidates in China in 2022.

According to Frost & Sullivan, B-cell CD19-positive acute lymphoblastic leukemia incidence in China grew at a CAGR of 1.6% from 8.8 thousand in 2015 to 9.4 thousand in 2019, and is expected to grow further at a CAGR of 1.5% from 9.6 thousand in 2020 to 10.2 thousand in 2024. Meanwhile, B-cell CD19-positive non-Hodgkin’s lymphoma incidence in China grew at a CAGR of 2.6% from 62.3 thousand in 2015 to 69.1 thousand in 2019, and is forecasted to grow further at a CAGR of 2.4% from 70.8 thousand in 2020 to 77.9 thousand in 2024, according to Frost & Sullivan. As of December 31, 2019, there were two CAR T-cell therapy drugs approved for sale outside of China with their global sales revenue totalling USD734 million in 2019. As of December 31, 2019, there was no CAR T-cell therapy drug approved for sale in China, while there were 12 CAR T-cell therapy drug candidates at clinical stages in China, according to Frost & Sullivan.

We are collaborating with Immunochina on the development and commercialization of such product candidates. Please see “– Our Collaboration Arrangements.”



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## BUSINESS

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### 4. BCMA CAR T-cell Therapy

BCMA CAR T-cell therapy is an innovative genetically modified cell therapy for the treatment of r/r multiple myeloma. BCMA CAR T-cells specifically recognize and target B cell maturation antigen (BCMA), a cell surface protein predominantly expressed on malignant plasma cells, and kill tumor cells. Investigator-initiated clinical trials have shown an ORR of 88% and a CR of over 50% on patients with r/r myeloma. We have obtained the IND approval for this product candidate and plan to initiate phase I clinical trials in China in the second half of 2020. We expect to submit the NDA for this product candidate in China in 2023.

According to Frost & Sullivan, multiple myeloma incidence in China grew at a CAGR of 3.1% from 18.3 thousand in 2015 to 20.7 thousand in 2019 and is expected to further grow further at a CAGR of 2.8% from 21.3 thousand in 2020 to 23.8 thousand in 2024.

We are collaborating with PREGENE on the development and commercialization of this product candidate. Please see “– Our Collaboration Arrangements.”

### *Central Nervous System Product Candidates*

#### 1. Edaravone and dexborneol concentrated solution for injection (依达拉奉右莰醇注射用濃溶液)

Edaravone and dexborneol concentrated solution for injection is our innovative chemical drug candidate which we have been developing in-house. It is a compound of edaravone and dexborneol with a proven ratio of 4:1. Edaravone is an antioxidant and a free radical scavenger which scavenges hydroxyl free radical (OH), nitric oxide free radicals (NO) and peroxynitrite anion (ONOO<sup>-</sup>); while dexborneol is a bicyclic monoterpene which could inhibit the production or expression of pro-inflammatory cytokines such as TNF- $\alpha$  and interleukin-1 $\beta$  as well as inflammation-related proteins such as cyclo-oxygenase-2 and induced nitric oxide synthase. With its dual mechanism of action, edaravone and dexborneol concentrated solution for injection scavenges free radicals, inhibits inflammatory response and improves the permeability in blood-brain barrier, minimizing brain injury or impairment caused by acute ischemic stroke. A randomized, double-blind, positive controlled, head to head comparison phase III study in approximately 1,200 acute ischemic stroke patients has shown that, compared to edaravone monotherapy, edaravone and dexborneol concentrated solution for injection has significantly higher efficacy with similar safety profile, extending the therapeutic time window from 24 hours to 48 hours. We have filed the NDA in China for our edaravone and dexborneol concentrated solution for injection in October 2018 and expect to obtain the approval in the third quarter of 2020. As of December 31, 2019, our edaravone and dexborneol concentrated solution for injection was the only edaravone and dexborneol concentrated solution for injection that had filed the NDA worldwide, according to Frost & Sullivan.

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## BUSINESS

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### 2. Y-2 sublingual tablets (Y-2舌下片)

Y-2 sublingual tablets are the solid dosage form of edaravone dexborneol compound. Sequential therapy consisting of Y-2 sublingual tablets and edaravone and dexborneol concentrated solution for injection is designed to enable patients to receive a timely and complete treatment. In addition, administration of sublingual tablets is less dependent on medical conditions or compliance of patients, which makes it more suitable for research on new indications such as other chronic central nervous system diseases. Further, sublingual tablets have higher commercial value due to its lower production and transportation costs and larger patient base. We are currently conducting phase I clinical trials for Y-2 sublingual tablets in China and expect such clinical trials to be completed in the second half of 2020. We plan to initiate phase II clinical trials in China in 2021.

We are collaborating with YenePharma and its affiliates on the development and commercialization of this product candidate. Please see “– Our Collaboration Arrangements.” YenePharma has initiated phase I clinical trials for Y-2 sublingual tablets in the United States.

### 3. SIM-307

SIM-307 is a first-in-class compound developed based on the Nobel-prize winning water channel discovery. SIM-307 is a potent inhibitor of aquaporin-4 (AQP4) water channels intended for treatment of cerebral edema caused by acute ischemic stroke through intravenous infusion administration. Studies have demonstrated SIM-307 as an AQP4 inhibitor to be effective in control of cerebral edema. We are currently preparing for IND application for this product candidate and expect to initiate phase I clinical trials in China in 2021.

According to Frost & Sullivan, the incidence of clinically significant cerebral edema in China grew from 551.3 thousand in 2015 to 677.5 thousand in 2019, and is expected to grow further at a CAGR of 3.1% from 2020 to 2024, reaching 793.4 thousand in 2024. As of December 31, 2019, there was no AQP4 inhibitor approved for sale worldwide, and no AQP4 inhibitor candidate was at clinical stage in China, according to Frost & Sullivan.

We are collaborating with Aeromics on the development and commercialization of this product candidate. Please see “– Our Collaboration Arrangements.” Aeromics has completed phase I clinical trial for SIM-307 in the United States.

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## BUSINESS

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### *Autoimmune Product Candidates*

#### *1. Abatacept Injection (阿巴西普注射液)*

Abatacept injection is for the treatment of moderate to severe rheumatoid arthritis. Abatacept injection is the first and only soluble CTLA4-Fc fusion protein approved for sale in China and the first and only selective T-cell co-stimulation modulator in the autoimmune disease therapeutic area worldwide, according to Frost & Sullivan. It prevents the activation of T cells by binding to the natural ligands CD80 and CD86 on antigen-presenting cells, thereby blocking their interaction with CD28 on the T cells, and consequently reduces inflammation. It may be used in combination with other DMARDs other than TNF- $\alpha$  inhibitors, such as methotrexate, to treat moderate to severe active rheumatoid arthritis patients who do not respond favorably to other DMARDs. Abatacept injection was developed by BMS and first approved for sale in the United States in 2005 under the Orencia® brand. It has also been launched in Europe and Japan with global sales of US\$3.0 billion in 2019, according to Frost & Sullivan. Abatacept injection obtained the IDL in China in January 2020.

According to a US claims database, the risk of hospitalized infection of patients who use abatacept injection was 22.6% lower than the commonly used TNF- $\alpha$  inhibitors. According to a head-to-head comparison study in 2014, abatacept injection, when used in combination with methotrexate, indicates similar efficacy and higher safety profile compared with adalimumab, a TNF- $\alpha$  inhibitor, when used in combination with methotrexate for treatment of rheumatoid arthritis patients. In June 2019, BMS announced data from a Phase IV mechanistic study exploring the differences between abatacept and adalimumab in interfering with disease progression in early moderate to severe rheumatoid arthritis patients seropositive for HLA-DRB1 shared epitope alleles. Trial results have shown higher efficacy responses from patients treated with abatacept.

We have been collaborating with BMS on the development and commercialization of abatacept injection in China. Please see “– Our Collaboration Arrangements” for more details.

#### *2. Iguratimod Tablets (Sjögren’s syndrome) (艾拉莫德片(干燥综合征))*

Iremod (iguratimod tablets), one of our major products, is an innovative chemical drug currently used for the treatment of active rheumatoid arthritis. As iguratimod can inhibit the generation of inflammatory cytokines and stimulate the generation of immunoglobulins, we are developing a new indication of iguratimod tablets for treatment of primary Sjögren’s syndrome. According to investigator-initiated clinical trials, iguratimod tablets, when used in combination with methylprednisolone, have demonstrated higher efficacy and faster onset than conventional therapy of using hydroxychloroquine in combination with methylprednisolone, without increased incidence of adverse events. Iguratimod tablets have been recommended by the “Primary Sjögren’s Syndrome Diagnosis and Treatment Standards” (《原发性干燥综合征诊疗规范》) issued by the Chinese Medical Doctor Association (中國醫師協會) in 2020. We are currently preparing for the IND application for iguratimod tablets for the indication of Sjögren’s syndrome in China.

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## BUSINESS

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According to Frost & Sullivan, prevalence of Sjögren’s syndrome in China grew from 8.2 million in 2015 to 8.4 million in 2019, and is forecasted to grow further to 8.6 million in 2024.

### 3. *SIM-335*

SIM-335, our innovative chemical drug candidate which we have been developing in-house, is intended for the treatment of mild to moderate plaque psoriasis through topical administration. SIM-335 regulates the differentiation of T helper cells 17 and significantly inhibits the secretion and expression of interleukin-17A, an inflammatory cytokine in psoriatic lesions. Meanwhile, SIM-335 inhibits the proliferation of keratinocytes while it also induces their differentiation, facilitates the normalization of epidermal keratinization, reduces the infiltration of inflammatory cells and thereby improves the symptoms and severity of psoriatic lesions. We have obtained IND approval for this product candidate in China and are currently in the preparation for phase I clinical trials.

According to Frost & Sullivan, prevalence of psoriasis in China grew from 6.5 million in 2015 to 6.6 million in 2019, and is forecasted to grow further to 6.8 million in 2024.

### 4. *SIM-295*

SIM-295 is a selective URAT1 inhibitor intended for the treatment of gout with hyperuricemia. URAT1 is a renal urate transporter localized to the apical (brush border) membrane of renal proximal tubular cells, where it mediates the re-absorption of uric acid from the proximal tubule, thereby playing a key role in uric acid homeostasis. By selectively inhibiting the re-absorption of uric acid by URAT1 and increasing the excretion of uric acid, URAT1 inhibitor can significantly control blood uric acid level and show therapeutic effect on gout. Early-stage clinical trials conducted in South Korea have observed promising efficacy and favorable safety profile. We plan to submit the IND application for this product candidate in China in 2020.

According to Frost & Sullivan, in recent years, gout prevalence in China shows an upward trend from 23.9 million in 2015 to 32.0 million in 2019, representing a CAGR of 7.6%, and is forecasted to grow further at a CAGR of 6.1% from 34.2 million in 2020 to 43.3 million in 2024. As of December 31, 2019, there was no selective URAT1 inhibitor approved for sale in China. Nevertheless, there were four selective URAT1 inhibitor candidates at clinical stages in China as of December 31, 2019, according to Frost & Sullivan.

We are collaborating with JW Pharmaceutical on the development and commercialization of this product candidate. Please see “– Our Collaboration Arrangements.” JW Pharmaceutical has initiated phase IIb clinical trials for SIM-295 in South Korea.

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## BUSINESS

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### *Generic Product Pipeline*

Our generic product pipeline centers around high entry-barrier and first-to-market generic pharmaceuticals with significant unmet clinical needs and market demand primarily in oncology, central nervous system disease and autoimmune disease therapeutic areas, while we also maintain a balanced pipeline of generic pharmaceutical candidates in other therapeutic areas. The major generic pharmaceuticals for which we expect to submit or obtain the generic drugs approval or IDL application in the next a few years are set out below:

- ***Oncology:*** Bevacizumab (貝伐珠單抗), bendamustine hydrochloride for injection (注射用鹽酸苯達莫司汀), lenvatinib mesilate capsules (甲磺酸倫伐替尼膠囊), palbociclib capsules (哌柏西利膠囊), ibrutinib capsules (伊布替尼膠囊), cabozantinib s-malate tablets (蘋果酸卡博替尼片) and relugolix tablets (瑞盧戈利片). For lenvatinib mesilate capsules and palbociclib capsules, we are the second to apply for the generic drugs approval (category IV generic pharmaceutical) in China, according to Frost & Sullivan;
- ***Central nervous system diseases:*** Batroxobin injection (巴曲酶注射液);
- ***Autoimmune diseases:*** Tofacitinib citrate tablets (枸橼酸托法替布片), celecoxib capsules (塞來昔布膠囊) and apremilast tablets (阿普斯特片). We have obtained the ANDA approval for celecoxib capsules in the United States from the U.S. Food and Drug Administration. We are the second to apply for the generic drugs approval (category IV generic pharmaceutical) in China for apremilast tablets, according to Frost & Sullivan, which has been included in the “List of the Overseas New Drugs Urgently Needed in Clinical Settings” (《臨床急需境外新藥名單》); and
- ***Others:*** Cinacalcet hydrochloride tablets (鹽酸西那卡塞片), sevelamer carbonate tablets (碳酸司維拉姆片), voriconazole for injection (注射用伏立康唑), posaconazole injection/enteric-coated tablets/oral suspension (泊沙康唑注射液/腸溶片/口服混懸液). For cinacalcet hydrochloride tablets and sevelamer carbonate tablets, we are the third to apply for the generic drugs approval (category IV generic pharmaceutical) in China, according to Frost & Sullivan. Moreover, our high end generic pharmaceutical candidates in other therapeutic areas also include salmeterol xinafoate and fluticasone propionate powder for inhalation (沙美特羅替卡松吸入粉霧劑) (clinical stage), nifedipine controlled-release tablets (硝苯地平控釋片) (generic drugs approval applied) and ferric carboxymaltose injection (羧基麥芽糖鐵注射劑) (CMC stage). We are the second to apply for the generic drugs approval (category IV generic pharmaceutical) for nifedipine controlled-release tablets, according to Frost & Sullivan, which utilize osmotic pump laser-beam drilling technology.

In particular, we are collaborating with Amgen for the development, manufacturing and commercialization of our biosimilar product candidate to bevacizumab, which is intended for the treatment of advanced non-squamous NSCLC. Please see “– Our Collaboration

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## BUSINESS

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Arrangements.” Bevacizumab is a recombinant fully-humanized monoclonal antibody that inhibits angiogenesis (the formation of new blood vessels) by blocking the action of VEGF and depresses the growth of solid tumors. The global sales of bevacizumab reached US\$7.12 billion in 2019, according to Frost & Sullivan, while bevacizumab biosimilars have been launched in Europe and the United States. We are currently conducting pivotal registrational trials for this product candidate in China and expect to file the IDL application in 2022. According to Frost & Sullivan, the first bevacizumab biosimilar in China was launched in 2020 and sales revenue of the bevacizumab biosimilar market in China is expected to reach RMB7.7 billion in 2025.

### RESEARCH AND DEVELOPMENT

#### In-House Research and Development

Our research and development activities are primarily conducted through our three R&D centers in China, one in Shanghai, which primarily focuses on innovative pharmaceuticals; one in Nanjing, Jiangsu Province, which primarily focuses on innovative and high entry-barrier generic pharmaceuticals; and one in Boston, the United States, which focuses on innovative and advanced therapies, particularly cell therapy.

Our R&D team comprised of experts with extensive experience in drug discovery, pre-clinical development, pilot scale production, clinical development and drug registration regulatory affairs, covering the entire R&D cycle. We primarily rely on our R&D team for the development of drug candidates, ultimately bringing them to market in a timely and cost-effective manner. As of December 31, 2019, our R&D department consisted of 699 full-time employees, 292 of whom held master’s degrees and 113 held Ph.D. degrees, featuring project leaders for NHFPC’s “Major New Drug Creation” Science and Technology Major Projects (「重大新藥創制」科技重大專項). Over 10% of our employees in R&D department are scientists or former R&D personnel from overseas well-known pharmaceutical companies or universities.

Our R&D team maintains close interaction with our production and sales and marketing teams to advance our research and development projects in an efficient manner. For example, our production and sales and marketing teams participate early in our research and development process, which enables us to reduce the risk of unanticipated technological obstacles in the manufacturing stage and focus on projects with attractive market potential. In addition, our R&D team assists our production team in resolving technical issues and improving manufacturing processes and techniques.

As an innovation-driven pharmaceutical company, we were approved by the Ministry of Science and Technology of the PRC in October 2015 to establish the only national key laboratory of translational medicine and innovative pharmaceuticals (轉化醫學與創新藥物國家重點實驗室) in the PRC pharmaceutical industry. This laboratory focuses on the translational medicine and precision medicine-based research and development of innovative pharmaceuticals for the treatment of oncology, central nervous system diseases, autoimmune diseases and infectious diseases. As part of the national strategy to promote technological



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## BUSINESS

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innovation, this laboratory is expected to (i) facilitate our participation in government-sponsored pharmaceutical research and development programs, (ii) facilitate our collaboration with hospitals and research institutions, and (iii) increasingly attract top talent worldwide to join our R&D team, and ultimately improving the speed, performance and efficiency of our research and development.

In 2017, 2018 and 2019, our research and development expenses were RMB212.3 million, RMB447.1 million and RMB716.4 million, representing 5.5%, 9.9% and 14.2% of our total revenue, respectively. See “Financial Information – Description of Key Statements of Profit or Loss Items – Research and Development Costs” for more details about our research and development expenses. Our research and development capabilities have been recognized by various levels of the PRC government. See “-Awards and Recognitions” for more details. We plan to continue to strengthen our R&D capabilities by attracting an increasing number of talents with extensive experiences in the relevant therapeutic areas or segments to join our R&D team.

### **Collaboration with Research and Development Partners**

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 in-license or co-develop innovative and high end generic drug candidates that have high potential for commercialization in China. These strategic partnerships further broaden our access to competitive drug candidates, while minimizing costs and risks associated with their early-stage research and development. We believe our in-house R&D capabilities, proven track record of successful development and commercialization of innovative pharmaceuticals, combined with our established manufacturing and commercial capabilities, have made us an attractive partner of choice for domestic and international pharmaceutical companies and biotechnology companies seeking to unlock the value of their assets in the rapidly growing PRC pharmaceutical market. In addition, we engage in joint R&D collaborations with universities and other research institutions.

Our external R&D partners include (i) leading domestic and multinational pharmaceutical companies such as BMS and Amgen; (ii) dynamic domestic and international biotechnology companies such as Apexigen, Aeromics, Merus, JW Pharmaceutical, GI Innovation, Primary Peptides, Jiangsu Alphamab, 3D Medicines Beijing, Immunochina, TCR Cure Beijing, PREGENE and YenePharma; and (iii) leading domestic and international universities and other research institutions such as Shanghai Jiao Tong University and Nanjing Medical University.

We collaborate with our external R&D partners pursuant to the relevant long-term collaboration agreements, the terms of which vary on a project-by-project basis. Our collaboration agreements generally provide us with an exclusive right to develop and commercialize the relevant product candidates within the designated geographic areas. We are normally responsible for the full development and commercialization cycle of the relevant product candidates in the designated areas at our cost or pursuant to cost-sharing arrangements, and in some instances, with necessary assistance from our R&D partners at certain stages (such

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## BUSINESS

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as the supply of APIs or finished products). We generally pay these R&D partners upfront payments, milestone payments and/or fixed-term royalties in accordance with the collaboration agreements, while in some cases, we may be entitled to receive royalties in connection with the transfer, license or commercialization of the relevant product candidate outside of the designated areas. We generally own any intellectual properties solely developed by us in the course of our collaboration and jointly own any jointly-developed intellectual properties. For details about our collaboration arrangements in relation to certain of our key product candidates, please see “– Our Collaboration Arrangements.”

Collaboration with external R&D partners is a major component of our R&D strategy. Our dedicated business development team has a deep understanding of our R&D strategies, extensive industry resources and experience as well as insightful observations in respect of industry trends. Our business development force is strategically located in our Nanjing headquarters, the United States and Great Britain, and they actively seek potential domestic and overseas collaboration opportunities by regularly participating in academic conferences, seminars and symposia regularly. As of December 31, 2019, our business development team consisted of 22 employees, who possessed an average of seven years of industry-related experience.

### CROs

In line with industry practice, we engage Independent Third Party CROs to support our product development. Our CROs provide us with an array of services, which primarily include molecule discovery, in vitro biological assays, analytics, formulation and process development, clinical monitoring and project management, data collection and management, statistics analysis, biological sample management and report preparation, or a combination of these services.

We select CROs based on their qualifications, reputation and accomplishments, including good laboratory practice qualifications issued by the NMPA, experience in conducting pre-clinical or clinical research on similar pharmaceutical products, research and project management capabilities and resources, as well as their testing facilities.

We generally enter into framework agreements with our CROs and we have executed statements of work for on a project basis. Key terms of such agreements and statements of work are summarized as follows:

- **Services.** The CROs provide us with specified services related to product development.
- **Term.** The CROs are required to complete their product development services at an acceptable quality within the prescribed time limit.

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## BUSINESS

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- ***Payments.*** We generally pay our CROs fixed amount service fees and, in some cases, together with incentive fees contingent upon the satisfaction of certain specified conditions, such as the success in obtaining NMPA approval within the stipulated time limit. We are required to make payments to the CROs in accordance with the payment schedules agreed by the parties.
- ***Adverse drug events.*** In the event of any serious adverse drug event arising during a clinical trial, we are generally responsible for the medical treatment expenses of, and monetary compensation (if any) to, the relevant trial subjects.
- ***Intellectual property rights.*** All intellectual property rights arising from the product development project will be owned by us upon completion of the project.

We closely monitor and manage the activities of these CROs to ensure their progress and quality, including (i) requiring CROs to comply with GCP requirements; (ii) comprehensive review and analysis of laboratory tests and clinical trial results and reports; and (iii) engaging third parties to audit the CROs.

### Research and Development Process

Before commencing a research and development project, we perform thorough market analysis to determine whether the product candidate has unmet medical needs in China, is commercially viable, is expected to be able to achieve widespread acceptance in the marketplace, and for a generic drug candidate, whether the market for the drug will have high barriers to entry and the drug will be the first generic version on the market. We carefully select research and development projects by balancing the unmet medical needs and commercial potential (including potential competition and market size) of the drug and its likelihood of successful development.

Each of our research and development projects is subject to the approval of our project committee which consists of members of our senior management team and senior R&D personnel. Our senior management team reviews the results of feasibility studies on product candidates and makes the final decision on whether to initiate a new development project. When the project is approved, a project code will be assigned and a project leader who, in turn, determines the project team members, will be nominated. The project leader is responsible for implementation of the project, including coordination with the various other departments involved, such as our intellectual property and project management departments. We also conduct monthly reviews of our ongoing research and development projects and may decide to discontinue projects that fail to make satisfactory progress or when there is a material adverse change to the competitive environment.

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## BUSINESS

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Our pharmaceutical product development process typically involves the following milestone stages and the actual timing of each stage could vary significantly depending on the subject and nature of the project and the resources committed to the project:

Development stage	Description
Pre-clinical	<ul style="list-style-type: none"><li>• Discovery of lead molecules through evaluation under screening platform, biological assays and pharmacokinetics assays</li><li>• Optimization of lead molecules and identification of clinical trial samples via pharmacology studies, pharmacokinetics studies and safety assessments</li><li>• Development of formulation strategies and manufacturing processes</li><li>• Characterization of clinical trial samples, identification of critical quality attributes and performance of stability studies</li><li>• Manufacturing of clinical trial samples</li></ul>
IND application	<ul style="list-style-type: none"><li>• Application for pre-IND communication</li><li>• Submission of IND application</li></ul>
Phase I clinical trials	<ul style="list-style-type: none"><li>• Human pharmacokinetics and drug tolerance evaluation trials</li><li>• For category I innovative drug candidates, the minimum number of cases required by NMPA for each trial group is 20 to 30</li></ul>
Phase II clinical trials	<ul style="list-style-type: none"><li>• Preliminary exploration on the therapeutic efficacy</li><li>• Dosage finding for phase III clinical trials</li><li>• For category I innovative drug candidates, the minimum number of cases required by NMPA for each trial group is 100</li></ul>

## BUSINESS

Development stage	Description
Phase III clinical trials	<ul style="list-style-type: none"> <li>• Confirmation of the therapeutic efficacy and safety</li> <li>• For category I innovative drug candidates, the minimum number of cases required by NMPA for each trial group is 300</li> </ul>
NDA	<ul style="list-style-type: none"> <li>• Application for approval of new drug registration from the NMPA</li> <li>• Review of the application materials, on-site inspections and final assessments by the NMPA</li> </ul>
Launch	<ul style="list-style-type: none"> <li>• NMPA approval for new drug registration is obtained; new drug certificate and drug approval number are granted</li> <li>• Mass production commences</li> </ul>
Phase IV clinical trials	<ul style="list-style-type: none"> <li>• Focused on delineating additional information about the drug, including side effects, long-term efficacy/risks and optimal use method</li> <li>• May result in a drug being taken off the market or additional restrictions being placed on the drug depending on the findings in the trials</li> </ul>

See “Regulatory Overview – Laws and Regulations Relating to Drugs – Laws and Regulations on Drug Registration” for further details about the laws and regulations relating to the registration of pharmaceutical products in the PRC.

## OUR COLLABORATION ARRANGEMENTS

### Oncology

#### *Apexigen License and Collaboration Agreement for Sevacizumab*

On December 12, 2008, we entered into a license and collaboration agreement with Epitomics, Inc., which was later assigned by Epitomics, Inc. to Apexigen in connection with a spinout from Epitomics, Inc. in 2010 (such license and collaboration agreement, the “**Apexigen License and Collaboration Agreement**”) to co-develop and commercialize a humanized anti-human VEGFa rabbit monoclonal antibody, namely, sevacizumab, for oncology therapeutics in humans.

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## BUSINESS

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We are responsible for, among other things, pre-clinical and clinical trials and studies and obtaining regulatory governmental approvals for the commercialization of sevacizumab in mainland China, Hong Kong and Macau, while Apexigen has reserved the right for the same in other regions worldwide. In addition, we are responsible for all development costs in mainland China, Hong Kong and Macau, while all such costs in other regions worldwide are shared between Apexigen and us at an agreed-upon percentage. Upon receiving the necessary regulatory approvals, we will have the exclusive right to sell, market and otherwise commercialize sevacizumab in mainland China, Hong Kong and Macau, while we will be entitled to share the profits from any transfer, license or sales of sevacizumab outside of mainland China, Hong Kong and Macau at an agreed-upon percentage.

Apexigen is entitled to receive upfront payments, milestone payments and royalties from us. We agreed to pay Apexigen royalties based on net sales of sevacizumab in mainland China, Hong Kong and Macau for a prescribed time period commencing on the date of first commercial sale, subject to earlier termination of the Apexigen License and Collaboration Agreement.

Pursuant to the Apexigen License and Collaboration Agreement, we were granted an exclusive and non-sublicensable license to certain intellectual property rights owned by Apexigen for the development and commercialization of sevacizumab in the field of oncology therapeutics in mainland China, Hong Kong and Macau; while we have granted Apexigen a non-exclusive, royalty-free and non-sublicensable license to inventions or other improvements derived from sevacizumab using intellectual property rights licensed from Apexigen (i) in mainland China, Hong Kong and Macau and outside the field of oncology therapeutics and (ii) outside of mainland China, Hong Kong and Macau. Any inventions conceived and reduced to practice in connection with the collaboration on sevacizumab are jointly owned by both parties. The Apexigen License and Collaboration Agreement will expire upon the later of (i) the expiration of the last valid patent claim under the licensed intellectual property rights; or (ii) a mid-teens number of years after the last commercialization of sevacizumab; unless there is an earlier termination by Apexigen or us. The Apexigen License and Collaboration Agreement may be terminated (i) by us upon the occurrence of any of certain specified conditions, including an effective judgement by a court in China adjudicating that sevacizumab infringes a third party patent; or (ii) by the non-defaulting party in the event of a material breach that is not remedied within a prescribed time period.

### ***Immunochina License and Collaboration Agreement for CD19 CAR T-cell Therapies***

We entered into a license and collaboration agreement with Immunochina and its affiliates on March 27, 2020 (the “**Immunochina License and Collaboration Agreement**”), pursuant to which Immunochina has (i) assigned us certain of its intellectual property rights that are necessary for the research, development, registration, manufacturing, promotion, delivery and commercialization of CD19 CAR T-cell therapies in the Asia-Pacific region; and (ii) licensed us certain of its platform intellectual property rights that are reasonably necessary for the research, development, registration, manufacturing, promotion, delivery and commercialization of CD19 CAR T-cell therapies in the Asia-Pacific region.



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## BUSINESS

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Pursuant to the Immunochina License and Collaboration Agreement, Immunochina is responsible for the pre-clinical studies of CD19 CAR T-cell therapies in the Asia-Pacific region, certain investigator-initiated clinical trials of CD19 CAR T-cell therapies in the Greater China, as well as the development, NDA and commercialization of CD19 CAR T-cell therapies outside of the Asia-Pacific region. We are responsible for the IND filings, registrational clinical trials, NDA and commercialization of CD19 CAR T-cell therapies in the Asia-Pacific region, except that Immunochina is responsible for certain IND filings it submitted prior to the Immunochina License and Collaboration Agreement as well as the phase I registrational clinical trials of CD19 CAR T-cell therapies in the Greater China for the indication of r/r CD19 positive non-Hodgkin's lymphoma, with the relevant costs to be shared between both parties in an agreed-upon manner.

Immunochina shall receive upfront payments, milestone payments as well as royalties from us. We have agreed to pay royalties to Immunochina based on net sales for a prescribed time period commencing from the launch of CD19 CAR T-cell therapies in the Asia-Pacific region, subject to further extension in accordance with the Immunochina License and Collaboration Agreement. We are responsible for the application and registration of trademarks and industrial designs of CD19 CAR T-cell therapies in the Asia-Pacific region, and will retain full ownership of these intellectual property rights once they are registered. In addition, pursuant to the Immunochina License and Collaboration Agreement, each party owns any intellectual property rights developed solely by it, while any intellectual property rights jointly developed are to be jointly owned.

The Immunochina License and Collaboration Agreement may be terminated (i) by either party in the case of bankruptcy, liquidation, dissolution or ceasing operations of the other party; (ii) by the non-defaulting party in the event of a breach that is not remedied within a prescribed time period; (iii) by us in the event that any inaccurate or misleading representations, warranties or commitments relating to the intellectual property rights of CD19 CAR T-cell therapies made by Immunochina which lead to material obstacles to the continuing performance of such agreement; or (iv) by us in the event that clinical trials are terminated by relevant government authorities due to safety or ethical reasons. Upon termination of the Immunochina License and Collaboration Agreement, all rights and licenses assigned or granted by Immunochina to us will remain in effect, except when the termination is due to a breach by us, or if Immunochina has returned all payments paid by us prior to the termination due to their breach. In such cases, all rights and licenses assigned or granted to us shall cease and revert to Immunochina. In addition, subsequent to 36 months after the launch of CD19 CAR T-cell therapies in the Greater China, Immunochina is entitled to recover all its rights in connection with CD19 CAR T-cell therapies in the Asia-Pacific region when the annual net sales and year-on-year growth rate in the Greater China fail to achieve the prescribed minimum requirements. In such case, we are entitled to the return of upfront payments, milestone payments and royalties previously paid by us to Immunochina as well as the reimbursement of all development expenses incurred by us, with interest, within a prescribed time period.

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## BUSINESS

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### ***PREGENE License and Collaboration Agreement for BCMA CAR T-cell Therapy***

We entered into a license and collaboration agreement with PREGENE and its affiliates on February 27, 2020 (the “**PREGENE License and Collaboration Agreement**”), pursuant to which PREGENE has (i) assigned us its proprietary patents directly relating to the development, manufacturing and commercialization of BCMA CAR T-cell therapy; and (ii) licensed us certain of its platform patents indirectly relevant to the development, manufacturing and commercialization of BCMA CAR T-cell therapy.

Pursuant to the PREGENE License and Collaboration Agreement, PREGENE is responsible for, at its own costs, the pre-clinical studies and IND filing of BCMA CAR T-cell therapy in the Greater China, as well as the development, BLA/NDA and commercialization of the same outside of the Greater China. We are responsible for clinical trials and NDA, of BCMA CAR T-cell therapy in the Greater China at our own costs. Upon receiving regulatory approvals, we will have the exclusive right to commercialize BCMA CAR T-cell therapy in the Greater China.

PREGENE shall receive upfront payments, milestone payments as well as royalties from us. We have agreed to pay royalties to PREGENE based on net sales for a prescribed time period commencing from the launch of BCMA CAR T-cell therapy in the Greater China.

We are responsible for the application and registration of trademarks and industrial designs of BCMA CAR T-cell therapies in the Greater China, and will retain full ownership of these intellectual property rights once they are registered. In addition, pursuant to the PREGENE License and Collaboration Agreement, each party owns any intellectual property rights developed solely by it, while any intellectual property rights jointly developed are to be jointly owned.

The PREGENE License and Collaboration Agreement may be terminated (i) by either party in the case of bankruptcy, liquidation, dissolution or ceasing operations of the other party; (ii) by the non-defaulting party in the event of a breach that is not remedied within a prescribed time period; (iii) by us in the event that any inaccurate or misleading representations, warranties or commitments relating to the intellectual property rights of BCMA CAR T-cell therapy were made by PREGENE which lead to material obstacles to the continuing performance of such agreement; or (iv) by us in the event that clinical trials are terminated by the relevant government authorities due to safety or ethical reasons. Upon the termination of the PREGENE License and Collaboration Agreement, all rights and licenses assigned or granted by PREGENE to us will remain in effect, except when the termination is due to a breach by us. In such case, all rights and licenses assigned or granted to us shall cease and revert to PREGENE.

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## BUSINESS

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### *Collaboration Agreements for KN035*

We entered into a tripartite collaboration agreement with Jiangsu Alphamab and 3D Medicines Beijing, together with a separate marketing and promotion agreement with 3D Medicines Beijing, on March 30, 2020, in respect of KN035 (collectively, the “**KN035 Collaboration Agreements**”).

The KN035 Collaboration Agreements provide us with an exclusive promotion right in respect of oncology treatment indications of KN035 in mainland China. Pursuant to the KN035 Collaboration Agreements, Jiangsu Alphamab will manufacture, and 3D Medicines Beijing will sell, KN035 to our designated distributors, while we are entitled to receive promotion service fees on a monthly basis calculated with reference to the total purchases made by our distributors and based on rates stipulated in the Collaboration Agreements. Pursuant to the KN035 Collaboration Agreements, we are entitled to make final decisions in respect of general matters including the commercialization of KN035 in mainland China, while reserved matters such as the pricing of KN035 shall be agreed upon unanimously by all three parties. We have agreed to undertake annual minimum promotion requirements starting from the fourth year of our collaboration and will re-negotiate such requirements with Jiangsu Alphamab and 3D Medicines Beijing upon the expiration of each consecutive four-year period thereafter. In addition, the KN035 Collaboration Agreements provide us the right of first refusal for in-licenses or transfers of KN035 in respect of oncology treatment indications in mainland China.

### *Amgen Collaboration Agreement for Bevacizumab*

We entered into a collaboration agreement with Amgen on September 12, 2017 (the “**Amgen Collaboration Agreement**”) to collaborate on the development, manufacturing and commercialization of a bevacizumab biosimilar (the “**Bevacizumab Biosimilar**”) in mainland China. Pursuant to the Amgen Collaboration Agreement, Amgen remains solely responsible for the day-to-day development of the Bevacizumab Biosimilar in mainland China, while the relevant costs are shared with us based on an agreed-upon percentage. Upon obtaining applicable regulatory approvals, Amgen will be responsible for manufacturing the Bevacizumab Biosimilar at its own costs and supplying the Bevacizumab Biosimilar to us at prices calculated in accordance with the terms of the Amgen Collaboration Agreement, while we will be responsible for the distribution and commercialization of the Bevacizumab Biosimilar in mainland China at our own costs.

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## BUSINESS

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All right, title and interest in and to any inventions that constitute improvements, modifications or enhancements to the Bevacizumab Biosimilar will be solely owned by Amgen, while each party otherwise owns any other inventions made solely by it. The Amgen Collaboration Agreement may be terminated in its entirety by the non-defaulting party in the case of a material breach that is not remedied within a prescribed time period. The Amgen Collaboration Agreement also provides that collaboration on the Bevacizumab Biosimilar can be terminated: (i) by either party in the event of our non-approval of collaboration plans or budgets prepared by Amgen for the Bevacizumab Biosimilar; (ii) by either party if the development or commercialization activities for the Bevacizumab Biosimilar outside mainland China are terminated by Amgen in accordance with the terms of the Amgen Collaboration Agreement, unless otherwise prescribed in such agreement; (iii) by Amgen with a 90-day written notice if the purchase price for the Bevacizumab Biosimilar falls below the prescribed minimum level in the Amgen Collaboration Agreement for over two consecutive calendar quarters; or (iv) by us if we, with reasonable evidence, consider it no longer commercially viable to supply or commercialize the Bevacizumab Biosimilar for or in mainland China. Upon the termination of the Amgen Collaboration Agreement in its entirety or the termination of collaboration on the Bevacizumab Biosimilar, all rights and licenses granted by Amgen to us under the Amgen Collaboration Agreement for the Bevacizumab Biosimilar will terminate and revert to Amgen.

### Central Nervous System Diseases

#### *YenePharma Collaboration Agreement for Y-2 sublingual tablets*

We entered into a collaboration agreement with YenePharma and certain of its affiliates on September 28, 2019 (the “**YenePharma Collaboration Agreement**”), pursuant to which we and YenePharma agreed to co-develop an edaravone compound in sublingual tablet dosage form, namely, Y-2 sublingual tablets. Pursuant to the YenePharma Collaboration Agreement, we are responsible for the development of the Y-2 sublingual tablets at our own costs and obtaining applicable regulatory approvals for the commercialization of Y-2 sublingual tablets in the Greater China, while YenePharma is responsible for the same outside of the Greater China. Meanwhile, we have engaged YenePharma to conduct pre-clinical and clinical trials and studies for the commercialization of Y-2 sublingual tablets in the Greater China. Upon receiving the necessary regulatory approvals, we will have the exclusive right to manufacture, sell, license and otherwise commercialize the Y-2 sublingual tablets in the Greater China.

YenePharma is entitled to receive milestone payments and royalties from us. We agreed to pay YenePharma royalties based on the net sales of the Y-2 sublingual tablets in the Greater China. We may not transfer our interest in the Greater China without the written consent of YenePharma, while YenePharma may not transfer its interest outside of the Greater China without our written consent. The aforementioned transfer by either party is subject to the right of first refusal of the other party. In the event that YenePharma transfers or in-licenses its interest outside of the Greater China to any third parties, any profit from any such transfer or in-license will be shared between YenePharma and us in accordance with agreed-upon percentages specified in the YenePharma Collaboration Agreement.

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## BUSINESS

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We and YenePharma jointly own the patents in connection with the Y-2 sublingual tablets. The YenePharma Collaboration Agreement may be terminated by us in the event of a material breach by YenePharma that is not remedied within a prescribed time period. In particular, in the event that YenePharma breaches the YenePharma Collaboration Agreement by collaborating with any third party on the Y-2 sublingual tablets in the Greater China, our payment obligations to YenePharma will cease, while our intellectual property rights to the Y-2 sublingual tablets, our exclusive right to commercialize the Y-2 sublingual tablets in the Greater China and our right to share the profits generated from any transfer or in-license outside of the Greater China will remain in effect.

### *Aeromics Agreement for SIM-307*

We entered into a license agreement with Aeromics in October 2019 (the “**Aeromics License Agreement**”), pursuant to which we were granted an exclusive and sub-licensable license to research, develop, manufacture and commercialize an AQP4 inhibitor, namely, SIM-307, in the Greater China at our own costs. In addition, Aeromics is responsible for supplying us a certain quantity of APIs for our development of SIM-307. Aeromics is entitled to receive upfront payment, milestone payments as well as royalties from us. We agreed to pay Aeromics royalties based on the net sales of SIM-307 in the Greater China for a prescribed time period on a product-by-product and region-by-region basis. Meanwhile, we are entitled to agreed upon percentages of payment received by Aeromics for its sale or in-license of SIM-307 outside of the Greater China.

Aeromics has granted us an exclusive license for its patent rights in the Greater China for the development and commercialization of SIM-307. Subject to the terms of the Aeromics License Agreement, each party owns any inventions invented or developed solely in connection with SIM-307, while any inventions invented or developed jointly by both parties are to be jointly owned. The Aeromics License Agreement will expire, on a product-by-product and region-by-region basis, when no payment obligations are or will become due. Upon such expiration, all license granted by Aeromics to us will be fully paid, royalty free, perpetual and irrevocable. Nevertheless, the Aeromics License Agreement is subject to early termination (i) by the non-defaulting party in the case of a material breach that is not remedied within a prescribed time period; (ii) by Aeromics in the event of our late payment of any upfront payment; or (iii) by us without cause upon serving a 60-day prior written notice. Upon early termination of the Aeromics License Agreement, all licenses granted to us will cease.

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## BUSINESS

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### Autoimmune Diseases

#### *BMS License Agreement for Abatacept Injection*

We entered into a license agreement with BMS on June 13, 2013, as amended on May 10, 2019 (the “**BMS License Agreement**”). Pursuant to the BMS License Agreement, we have the co-exclusive right to develop and the exclusive right to commercialize a pharmaceutical product containing abatacept for rheumatoid arthritis, namely, abatacept injection, in mainland China at our own costs. BMS will manufacture and supply the abatacept injection (only in safety syringe form as finished goods) to us for commercialization in mainland China at agreed upon prices under a separate supply agreement entered into between BMS and us on May 10, 2019. We agreed to pay royalties to BMS based on the net sales of the abatacept injection in mainland China for a prescribed time period commencing on the date of the first commercial sale. Meanwhile, BMS may, by serving a written notice at any time during a 12-month period commencing on the date of the first commercial sale, exercise a one-time election to opt-in to the commercialization of the abatacept injection in mainland China. In such event, BMS will share the operating profits or losses with us according to the agreed-upon percentages and there will be no royalties payable to BMS by us for the sales of the abatacept injection in mainland China.

BMS solely owns all right, title and interest in and to any inventions that are directed to the composition, use, formulation or manufacture of, or an improvement to, the abatacept injection, that are invented or discovered under the BMS License Agreement. The BMS License Agreement may be terminated for various reasons, including (i) by the non-breaching party in the event of a material breach that is not remedied within a prescribed time period; (ii) by BMS in the case of our insolvency; or (iii) by us without cause at any time subsequent to the second anniversary of the date of the first commercial sale of the abatacept injection in mainland China upon serving a six-month written notice. In the event of any termination of the BMS License Agreement, all rights and licenses granted by BMS to us under such agreement will terminate and revert to BMS.

#### *JW Pharmaceutical License Agreement for SIM-295*

We entered into a license agreement with JW Pharmaceutical on September 27, 2019 (the “**JW Pharmaceutical License Agreement**”), pursuant to which we were granted an exclusive, sub-licensable and non-transferable right to develop and commercialize a URAT1 inhibitor for therapeutic use in gout with hyperuricemia, namely, SIM-295, in mainland China, Hong Kong and Macau at our own costs, as well as a right of first negotiation to obtain an exclusive right to develop and commercialize the same in Taiwan. We have the right to manufacture SIM-295 by ourselves or through a third-party contract manufacturer engaged by us for the purpose of the development and commercialization of SIM-295.



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## BUSINESS

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JW Pharmaceutical is entitled to receive upfront payments and milestone payments as well as royalties from us. We agreed to pay JW Pharmaceutical royalties based on the net sales of SIM-295 in mainland China, Hong Kong and Macau for a prescribed time period commencing on the date of the first commercial sale.

JW Pharmaceutical has granted us an exclusive license for its patent rights in mainland China, Hong Kong and Macau for the development and commercialization of SIM-295. Subject to the terms of the JW Pharmaceutical License Agreement, each party owns the intellectual property rights to any improvement developed solely in connection with SIM-295, while the intellectual property rights to any improvements jointly-developed by both parties are to be jointly owned. The JW Pharmaceutical License Agreement will expire upon the expiration of the royalty term, as a result of which, all rights and licenses granted by JW Pharmaceutical to us will be fully paid-up, perpetual and irrevocable. The JW Pharmaceutical License Agreement is also subject to early termination (i) by either party in the event of the bankruptcy of the other party; (ii) by the non-defaulting party in the case of a material breach that is not remedied within a prescribed time period; (iii) by JW Pharmaceutical in the event that we challenge the validity of licensed patents; or (iv) by us, without cause, upon serving a 120-day prior written notice. Upon the early termination of the JW Pharmaceutical Agreement, all rights granted to us will cease and we must return all data and information received from JW Pharmaceutical.

## PRODUCTION

### Production Process

We are capable of manufacturing pharmaceuticals in a variety of dosage forms, including injectables, oral liquids, oral solid dosage forms (tablets, capsules, granules and powders), implants, gel and dry powder for inhalation, in our production facilities. In addition, we produce a number of APIs in-house, some of which are used in the manufacturing of certain of our products including Iremod, Bicun, Newanti, Jepaso and Jiebaili.

Our production processes vary between each dosage form and product and the production time varies depending on the specific requirements of the product and production process. The production processes used in the manufacturing of our major products are set forth below.

#### *Production Process for Injectables*

Injectables that we manufacture in-house include both large molecule Injectables and small molecule injectables, which consist of injectable solutions, powder for injection and lyophilized powder for injection.

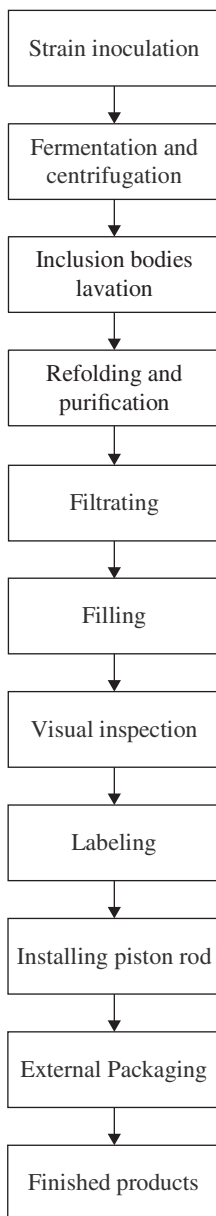
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## BUSINESS

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### *Large Molecule Antineoplastic Injectable Solutions*

The following diagram summarizes the production process for Endostar, which takes approximately 30 days.



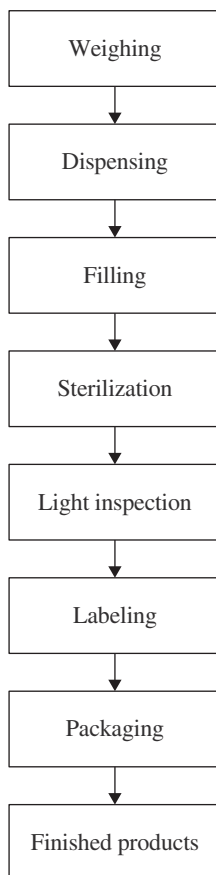
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## BUSINESS

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### *Small Molecule Injectable Solutions*

The following diagram summarizes the production process for Bicun, which takes approximately three days.



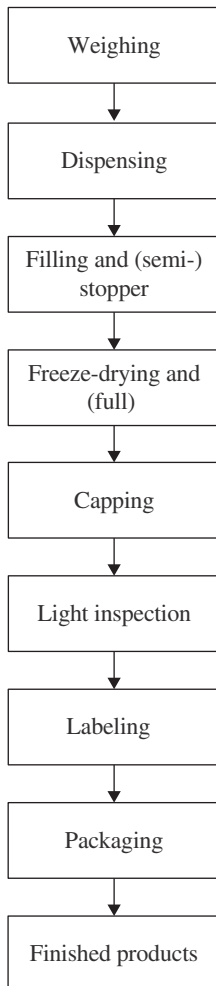
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## BUSINESS

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### *Small Molecule Antineoplastic Lyophilized Powder for Injection*

The following diagram summarizes the production process for Jepaso and Jiebaili, which ranges from approximately four to six days.



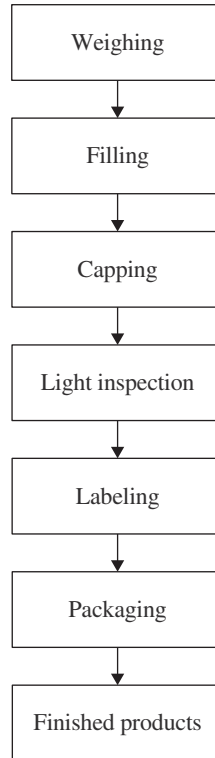
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## BUSINESS

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### *Small Molecule Powder for Injection*

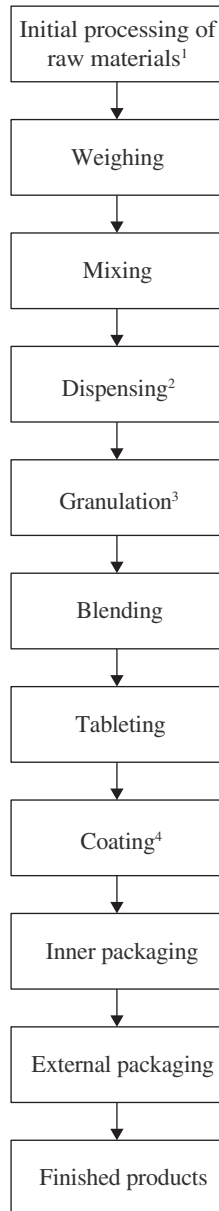
The following diagram summarizes the production process for Newanti, which takes approximately two days.



## BUSINESS

### *Production Process for Tablets*

The following diagram summarizes the production process for Iremod, Softan and ZAILIN dispersible tablets, which takes approximately five days.



*Notes:*

- (1) Not required for ZAILIN dispersible tablets;
- (2) Not required for Softan;
- (3) Not required for Softan and ZAILIN dispersible tablets;
- (4) Not required for Iremod and ZAILIN dispersible tablets.



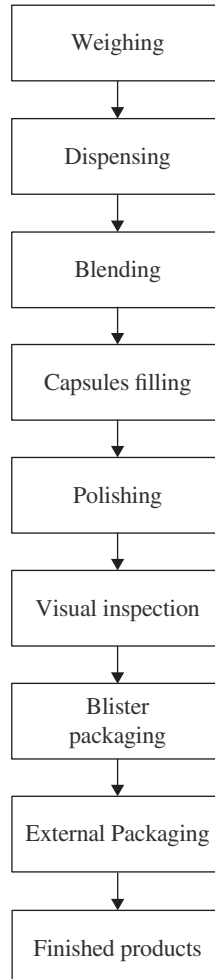
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## BUSINESS

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### *Production Process for Capsules*

The following diagram summarizes the production process for ZAILIN capsules, which takes approximately five days.



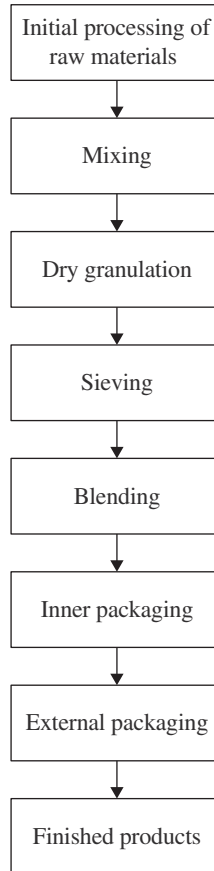
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## BUSINESS

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### *Production Process for Granules*

The following diagram summarizes the production process for ZAILIN granules, which takes approximately three days.



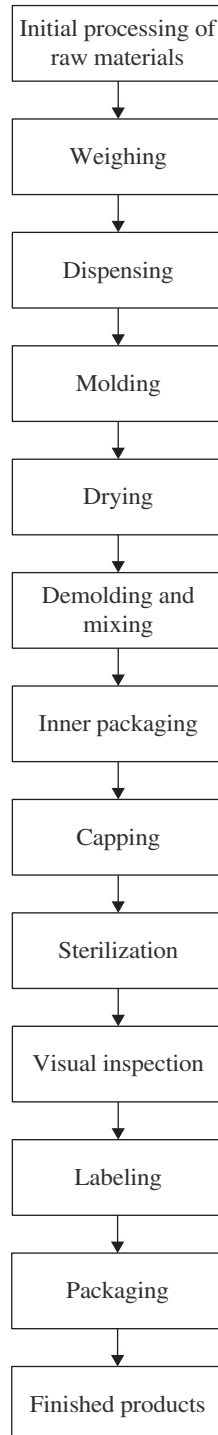
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## BUSINESS

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### *Production Process for Implants*

The following diagram summarizes the production process for Sinofuan, which takes approximately 27 days.



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## BUSINESS

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### Production Facilities

We currently have five production facilities for the manufacturing of our pharmaceutical products, including one located in Nanjing, Jiangsu Province (which also has API workshops), two located in Hainan Province (namely, Yaogu facility, which also has API workshops, and Chengmai facility), one located in Yantai, Shandong Province and one located in Wuhu, Anhui Province.

As of December 31, 2019, our production facilities occupied an aggregate site area of approximately 624,868 sq.m. and had an aggregate GFA of approximately 121,632 sq.m. Our production facilities house a total of 21 production lines, 14 of which produce oral medications including tablets, capsules, granules, powders and oral liquids, four of which produce injectables, one of which produces implants, one of which produces gel and one of which produces dry powder for inhalation. We also have five workshops for the production of APIs and one workshop for the extraction of traditional Chinese medicines.

During the Track Record Period and up to the Latest Practicable Date, we obtained production licenses for all of our production facilities, GMP certifications for all of our workshops and production lines used for the production of our existing pharmaceutical products, and production permits for each of our pharmaceutical products and APIs manufactured in-house. Please see “– Licenses, Permits and Certificates” for more details about our major licenses, permits and certificates.

Our production facilities are fully equipped with advanced automated equipment such as pneumatic filling machine (氣流分裝機), automated solution preparation, crystallizing and multi-function filtration drying automatic system (配料-結晶-多功能過濾乾燥全自動系統), tablet machine (壓片機), granulation machine (製粒機), fully-automatic packaging line (全自動包裝線), integrated washing-drying-filling line (洗烘灌聯動線), integrated light inspection and leak detection machine (燈檢檢漏一體機) and fully-automated solution preparation system (全自動配液系統). Our production equipment is generally aged from three years to 10 years. We carry out maintenance and repair work in compliance with applicable GMP requirements and we replace or upgrade our production equipment when necessary to enhance productivity. We believe our production facilities and equipment are in good working condition.

## BUSINESS

The following table sets forth the designed production capacity, actual production volume and utilization rates of the production lines which are used in the production of our major products as of the dates and for the periods indicated:

Production lines	Unit	As of/Year ended December 31,								
		2017			2018			2019		
		Designed production capacity	Production volume	Utilization rate (%) <sup>(1)</sup>	Designed production capacity	Production volume	Utilization rate (%) <sup>(1)</sup>	Designed production capacity	Production volume	Utilization rate (%) <sup>(1)</sup>
Large molecule injectable solutions	10,000 pre-filled syringes	217	129	59	272	176	65	435	218	50
Small molecule injectable solutions	10,000 ampoules	7,392	4,127	56	7,920	3,817	48	7,920	2,719	34
Small molecule powder for injection	10,000 vials	583	203	35	583	281	48	583	288	49
Small molecule lyophilized powder for injection	10,000 vials	410	179	44	410	310	76	410	374	91
Tablets	10,000 pills	92,622	25,289	27	92,622	44,363	48	92,622	54,868	59
Implants	10,000 vials	80	22	28	80	35	44	96	39	40
Capsules	10,000 pills	77,904	23,272	30	77,904	24,501	32	77,904	24,962	32
Granules	10,000 packs	55,289	32,883	60	55,289	36,512	66	55,289	33,856	61

*Note:*

- (1) Utilization rate is calculated by dividing the production volume by the designed production capacity. The fluctuations in our utilization rates generally reflect the fluctuations in our production volumes in line with the level of market demand for the corresponding products. During the Track Record Period, in anticipation of an increase in market demand for Endostar, Bicun and Sinofuan, we upgraded the production lines for large molecule injectable solutions and small molecule injectable solutions, and installed an additional inner packaging machine in the production line for implants, which resulted in increased annual designed production capacities of these production lines.

Our production plan is devised based on an annual, monthly and quarterly rolling forecasts of market demand at the beginning of each year with reference to historical sales records and anticipated level of sales orders, which will be adjusted in accordance with actual demand and inventory levels. See “– Inventory Management” for more details.

## BUSINESS

The following table sets forth a summary of our production facilities as of December 31, 2019:

Facility	Location	Site Area (sq.m.)	GFA (sq.m.)	Production Workshop	Production Line	Major Products Produced	API and Other Workshops
Nanjing facility	Nanjing, Jiangsu	145,436	53,475	Oral liquid workshop Solid dosage workshop  Antineoplastic powder for injection workshop  Powder for injection workshop  Small volume injectable solution workshop	Oral liquid production line Capsule production line Tablet production line Dry powder inhaler production line Small molecule antineoplastic lyophilized powder for injection production line Small molecule powder for injection production line Small molecule injectable solution production line	N/A <sup>(1)</sup>  N/A <sup>(1)</sup>  Softan  N/A <sup>(1)</sup>  Jepaso, Jiebaili  Newanti  Bicun	Three API workshops and one workshop for extraction of traditional Chinese medicines
Yaogu facility	Haikou, Hainan	152,188	28,594	Comprehensive workshop     Diosmectite powder workshop	Tablet production line Capsule production line Granule production line Gel production line Powder production line	Iremod  Yingtaiqing sustained- release capsules N/A <sup>(1)</sup>  Yingtaiqing gel N/A <sup>(1)</sup>	Two API workshops



## BUSINESS

Facility	Location	Site Area (sq.m.)	GFA (sq.m.)	Production Workshop	Production Line	Major Products Produced	API and Other Workshops
Chengmai facility	Chengmai, Hainan	259,371	18,897	Cephalosporin workshop	Oral suspensions production line Granule production line Capsule production line	N/A <sup>(1)</sup> N/A <sup>(1)</sup> N/A <sup>(1)</sup>	N/A
				Penicillin workshop	Oral suspension production line Granule production line Capsule production line Tablet production line	N/A <sup>(1)</sup> ZAILIN granules ZAILIN capsules ZAILIN dispersible tablets	
Yantai facility	Yantai, Shandong	47,873	17,599	Recombinant human endostatin injection workshop	Large molecule injectable solution production line	Endostar	N/A
Wuhu facility	Wuhu, Anhui	20,000	3,067	Implant workshop	Implant production line	Sinofuan	N/A

*Note:*

- (1) These production lines are designated for production of pharmaceutical products that are not our major products.

## BUSINESS

### *Expansion Plan*

We plan to increase our production capacity by constructing new production facilities, new production workshops and new production lines to meet the demand for our pharmaceutical products in different dosage forms. The following table sets forth additional details of our major expansion and upgrade plan for our production facilities:

Production facility	Production workshop	Description	Actual/estimated time of commencement of pilot-scale production <sup>(1)</sup>	Annual designed production capacity	Estimated total capital expenditures and source of funding
Nanjing facility	Small volume injectable solution workshop	Construction of a new production line for the production of terminal sterilized small molecule injectable solutions packaged in vials in our product pipeline	September 2020	26 million vials	– Approximately RMB19 million – Internal financial resources
Yaogu facility	A new lyophilized powder for injection workshop	Construction of a new production workshop for the production of non-antineoplastic small molecule lyophilized powder for injection in our product pipeline	March 2020	23 million vials	– Approximately RMB68 million – Internal financial resources

## BUSINESS

Production facility	Production workshop	Description	Actual/estimated time of commencement of pilot-scale production <sup>(1)</sup>	Annual designed production capacity	Estimated total capital expenditures and source of funding
	A new sterile injectable solution workshop	Construction of a new production workshop for the production of sterile small molecule injectable solutions packaged in ampoules in our product pipeline	August 2021	23 million ampoules	– Approximately RMB82 million – Internal financial resources
A new production facility in Nanjing	Large molecule pharmaceutical workshop	Construction of a new production facility for the production of mAbs and certain other biologics in our product pipeline (including both drug substances and products)	June 2020	– Drug substance: 34,000 liters; – Drug product: 3 million vials	– Approximately RMB0.2 billion – Internal financial resources
A new production facility in Shanghai	A new pilot-scale workshop for cell therapy products	Construction of a new workshop for CMC and clinical research of cell therapy products in our product pipeline (including the phase II clinical trial for BCMA CAR T-cell therapy)	January 2021	– Autologous cell therapy pharmaceuticals: for 300 to 400 people – Allogeneic cell therapy pharmaceuticals: for 2,000 people	– Approximately RMB60 million – Internal financial resources

## BUSINESS

Production facility	Production workshop	Description	Actual/estimated time of commencement of pilot-scale production <sup>(1)</sup>	Annual designed production capacity	Estimated total capital expenditures and source of funding
A new production facility in Shanghai	A new production facility for cell therapy products	Construction of a new production facility for the commercial-scale production of cell therapy pharmaceuticals in our product pipeline, such as CD19 CAR T-cell therapies and BCMA CAR T-cell therapy	– <sup>(2)</sup>	– For 2,000 to 3,000 people	– Approximately RMB150 million – Internal financial resources

*Note:*

- (1) Commercial-scale production in such production facilities will commence upon the launch of relevant product candidates.
- (2) This production facility will be constructed for commercial-scale production only.

We are constructing the new production facility, production workshop and production line above mainly due to special production process requirements for certain products in our pipeline. For example, our existing small molecule injectable solution production line in our Nanjing facility is only able to manufacture terminal sterilized small molecule injectable solutions packaged in ampoules, while some products in our pipeline are expected to be terminal sterilized small molecule injectable solutions packaged in vials or non-terminal sterilized small molecule injectable solutions packaged in ampoules. Our existing small molecule lyophilized powder for injection production line in our Nanjing facility is only able to manufacture antineoplastic pharmaceuticals, while some products in our pipeline are expected to be non-antineoplastic pharmaceuticals. In addition, our existing large molecule injectable solution production line in our Yantai facility is only able to manufacture pre-filled injectable solutions in pre-filled syringes,, while certain biologics in our product pipeline are in the form of lyophilized powder for injection or injectable solutions packaged in vials.

In addition, our existing production facilities are incapable for pilot-scale or commercial-scale production of cell therapy products, the manufacturing of which is complex and difficult due to the variability of collected cells from individual patients. We are currently constructing a new workshop for the pilot-scale production of cell therapy products in our product pipeline. With small scale and high flexibility, such pilot-scale production can adapt to various

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## BUSINESS

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production processes and thereby support CMC and clinical research of different cell therapy products. We also plan to construct a new production facility for the commercial-scale production of cell therapy products in our product pipeline in preparation for their commercial launch.

We believe the following factors substantiate sufficient market demand for the expected increase in our production capacity for injectables:

- the historical growth rates in our sales;
- our robust pipeline of product candidates and near-commercial products with significant market potential;
- our strategy to increase our market coverage through efficient academic marketing efforts;
- any unexpected increases in market demand for pharmaceuticals in our product portfolio; and
- our potential acquisitions in the future.

### **Raw Material Suppliers and Procurement**

The principal raw materials used for the production of our pharmaceutical products primarily consist of APIs, chemicals used to produce APIs, excipients and packaging materials. We source such raw materials primarily from third-party suppliers in China. We also produce certain APIs used in the manufacturing of our pharmaceutical products in-house, and we own the mining rights to a diosmectite mine that produces diosmectite, a raw material used in the manufacturing of Biqui.

We adopt stringent supplier selection procedures. Potential suppliers are assessed based on various factors including their product offerings, quality, corporate management, reputation and business scale and pricing. Our suppliers are required to possess all licenses and permits necessary for their operations. We also request potential suppliers to conduct small-batch sample production and inspect the samples to determine if they meet our requirements. Only those suppliers which fulfil all our requirements are selected. We maintain an approved suppliers list and we only source raw materials from these suppliers. We routinely review and assess our suppliers’ performance and check their qualifications to ensure the legality and quality of our raw materials, and update the approved suppliers list every three months. Those suppliers who fail to meet our requirements are removed from our approved suppliers list.

We generally place purchase orders with our raw material suppliers on an as needed basis and do not have agreements with them lasting longer than one year. Nevertheless, we are able to maintain long-term business relationships with most of our raw material suppliers. The purchase price of our raw materials is primarily based on the prevailing market prices for raw

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## BUSINESS

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materials of similar quality. We normally pay our suppliers via wire transfer or bank acceptance bills. Typically, we are required to make full prepayment, or are given at least 20 days’ credit terms, by our suppliers. Our suppliers are generally responsible for arranging the delivery of raw materials to our production facilities at their own costs. We are entitled to return any raw materials that do not meet our requirements.

Our principal raw materials are generally readily available in the market through a number of suppliers. We believe we have alternative sources for our principal raw materials with comparable quality and pricing. During the Track Record Period and up to the Latest Practicable Date, we did not experience any shortage or delay in the supply of raw materials.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any significant increases in the prices of our major raw materials or fluctuations in raw material costs which had a material adverse impact on our results of operations or gross profit margins. Please see “Risk Factors – Risks Relating to Our Business and Industry – 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.”

For the sensitivity analysis and breakeven analysis of the cost of raw materials, please see “Financial Information – Description of Key Statements of Profit or Loss Items – Cost of sales.”

### **Inventory Management**

Our inventory primarily consists of finished products, work in progress and raw materials. We have established an inventory management system that monitors each stage of the warehousing process. Our warehousing personnel are responsible for the inspection, storage and distribution of raw materials and finished products. All raw materials and products are stored in different areas in our warehouses according to their respective storage condition requirement, properties, usage and batch number. Our warehousing personnel regularly check to ensure consistency among the raw material or product, logbook and material card.

We closely monitor our inventory levels and generally keep one-to-three month stock of our finished products. We generally purchase raw materials based on their useful lives and required lead time. For raw materials with longer lead times, we generally maintain two to three months’ stock.

We make provision for inventories primarily with a shelf life of less than six months in accordance with HKFRS. As of December 31, 2017, 2018 and 2019, we made provision for impairment loss of our inventories in the amount of RMB6.6 million, RMB7.6 million and RMB5.6 million, respectively.



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## BUSINESS

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### QUALITY CONTROL

We believe that an effective quality control system is critical to ensure the quality of our products and maintaining our reputation and success. We have obtained GMP certifications for all of our workshops and production lines. We have also received EU GMP certification for the production of our Biqi-branded diosmectite powder in our Yaogu facility. In addition, we have passed the U.S. FDA inspection for our solid dosage form production workshop in our Nanjing facility. Our Yaogu facility and Nanjing facility have been granted ISO9001 certifications for their quality management systems.

Our senior management team is actively involved in formulating internal quality control policies and monitoring our overall quality control process. We have established comprehensive quality control procedures and protocols that span across the entire production lifecycle from raw material sourcing till the final products are delivered to customers. Our quality control personnel are independent from our production team and are responsible for the implementation of such procedures and protocols. Most of our quality control personnel have pharmaceutical or related educational background. We also conduct regular training so that our quality control personnel understand the regulatory requirements applicable to the operation of our production facilities. In addition, we utilize equipment and devices to inspect, test and ensure the quality of our raw materials, production-in-progress and final products.

Key aspects of our quality control procedures are as follows:

#### **Raw Material Quality Control**

We purchase raw materials used in our production only from approved suppliers. Please see “– Production – Raw Material Suppliers and Procurement” for more details about our supplier selection procedures.

We examine our incoming raw materials to confirm they meet our quality requirements. Our warehousing personnel verify the incoming raw materials by checking packaging information before taking delivery. Incoming raw materials are stored in quarantined areas upon receipt. Our quality control team subsequently selects samples for testing to verify the quality. Our warehousing personnel dispatch incoming raw materials for use in our production processes that have passed such quality control tests.

#### **Production In-process Quality Control**

Our advanced automated production equipment is able to screen out and discard semi-finished products that fail to meet quality standards during the production process. In addition, our quality control team conducts sample testing on certain semi-finished products at particular stages of production to ensure that they meet our quality standards, such as physical appearance (including the shape of capsules and granules), ingredient composition and drug content.

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## BUSINESS

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Our quality control team is responsible for verifying that our production processes continuously comply with GMP requirements. We require our production operators to adhere to our standard operating and equipment operation procedures and our quality control team regularly inspects our production processes on-site. After the completion of each production process, we perform cleaning procedures to prevent contamination or cross contamination, and our quality control team verifies that the production line has been properly cleaned before we proceed to the next production process. All of our cleaning procedures have been validated before their implementation.

### **Final Product Quality Control**

Each batch of final products is subject to a sample tests by our quality control team. Before we deliver our final products to customers, our quality control team inspects the documentation relating to the quality of a product, including its batch records, laboratory testing records, production process records and other information that may impact product quality. Our quality director conducts a final review of all documents and make the final decision as to whether the products can be released for sale. Final products that do not meet our quality standards can not be released and they are destroyed or otherwise disposed of based on the judgement of our quality director. Only final products that have been released by our quality control personnel can be sold into the market.

## **SALES, MARKETING AND DISTRIBUTION**

### **Overview**

We promote our pharmaceutical products primarily through our in-house sales and marketing team, which interacts with KOLs as well as other healthcare professionals through comprehensive academic marketing activities. We believe our academic marketing activities enhance healthcare professionals’ knowledge about the relevant therapeutic areas, as well as their understanding of the usage, clinical efficacy and other features of our products. We also engage third-party promoters to promote our products in a small number of medical institutions located in lower-tier cities or regions or that are otherwise not covered by our in-house sales and marketing team. In addition, we provide promotion services to certain other pharmaceutical manufacturers through our in-house sales and marketing team.

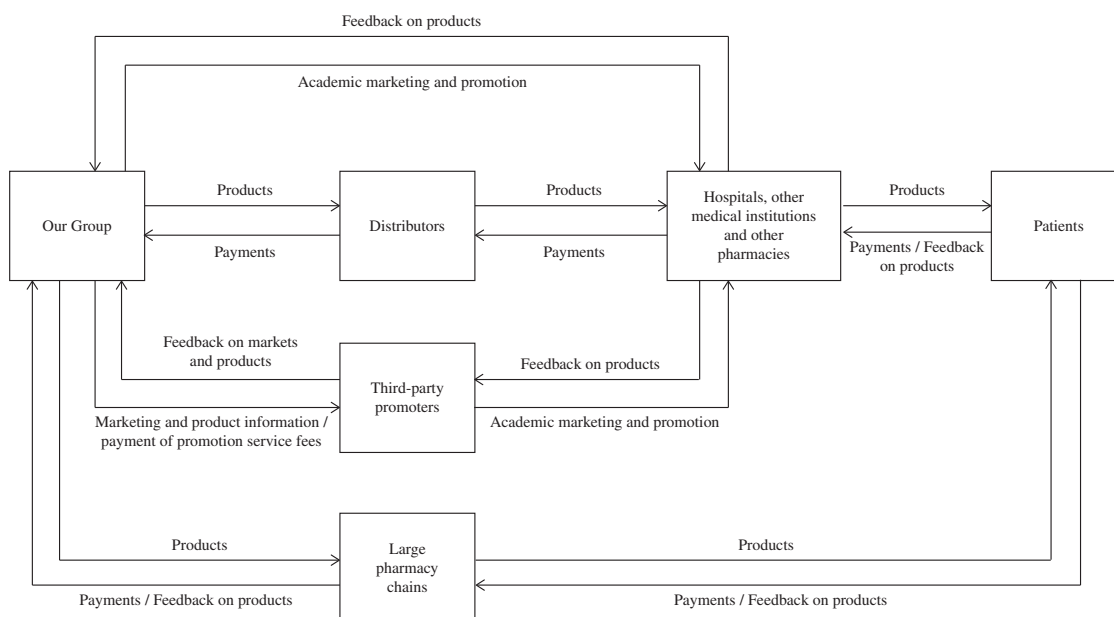
We sell our products and third-party products primarily to distributors, which distribute our products to hospitals, other medical institutions and pharmacies in China. To a lesser extent, we also sell our products and third-party products directly to large-scale national or regional pharmacy chains in China. During the Track Record Period, we also exported Biqui-branded diosmectite powder to overseas countries including France and Lithuania, through distributors.

## BUSINESS

The table below sets forth a breakdown of our revenue from sales of pharmaceuticals by distribution channels during the Track Record Period:

	Year ended December 31,					
	2017		2018		2019	
	<i>RMB'000</i>	<i>% of revenue</i>	<i>RMB'000</i>	<i>% of revenue</i>	<i>RMB'000</i>	<i>% of revenue</i>
Distributors	3,577,804	93.2	3,925,095	91.1	4,356,479	90.8
Direct sales	259,175	6.8	384,053	8.9	443,844	9.2
<b>Total</b>	<b>3,836,979</b>	<b>100.0</b>	<b>4,309,148</b>	<b>100.0</b>	<b>4,800,323</b>	<b>100.0</b>

The following diagram illustrates the interactions among our third-party promoters, distributors, hospitals and other medical institutions, pharmacies, patients and us in connection with sales, marketing and distribution of our pharmaceutical products in China:



### In-House Sales and Marketing Team

Our in-house sales and marketing team is primarily responsible for the promotion of our products through various academic marketing activities to hospitals and other medical institutions and direct sales to large-scale national or regional pharmacy chains. Our in-house sales force is organized by therapeutic areas and geographical regions. As of December 31, 2019, our in-house sales and marketing team included over 2,600 in-house employees spanning 31 provinces, municipalities and autonomous regions across China, covering approximately 1,900 Class III hospitals, approximately 17,000 other hospitals and medical institutions, as well as more than 200 large-scale national or regional pharmacy chains. As of the same date,

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## BUSINESS

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our core sales and marketing personnel had an average of over 10 years of pharmaceutical industry-related experience, and over 40% of them held bachelor’s degrees or above in medicine, pharmacy or related majors. We believe that an in-house sales and marketing team with a relatively high level of industry knowledge and expertise is important to implement our academic marketing approach and to maintain our reputation and brand image.

Our sales and marketing personnel are required to strictly adhere to our detailed procedures, policies and guidelines, including but not limited to a code of conduct on interacting with, and promoting our products to, healthcare professionals. Please see “Internal Control and Risk Management.”

### *Marketing Support*

Our in-house sales and marketing team works closely with several other departments at the headquarters level on the promotion of our products. We believe this centralized approach enables us to continuously enhance our brand recognition, market share and market penetration in an efficient manner.

- *Medical market department (醫學市場部)*. Our medical market department at the headquarters level is responsible for developing the overall sales and marketing strategies for each of our products. Before a product is launched, our medical market department conducts extensive market research and analysis and, based on the product’s clinical features and competitive positioning, establishes its branding strategies and tactics and allocates an adequate level of marketing resources. Our medical market department also provides our sales and marketing personnel with the medical information and academic data of our products to support our product promotion initiatives, which will be continuously updated over the relevant products’ life cycle.
- *Strategic account department (戰略客戶部)*. Our strategic account department at the headquarters level supports our sales and marketing efforts by (i) analyzing applicable laws and regulations in China’s pharmaceutical industry and formulating corresponding growth strategies in a timely manner, (ii) when suitable opportunities arise, procuring our products’ entry into the NRDL or other government-sponsored medical insurance programs, and (iii) preparing tender documents and participating in the centralized tender process.
- *Commercial Operation Management Center (營銷管理中心)*. Our commercial operation management center at the headquarters level is responsible for managing the overall effectiveness of our sales and marketing initiatives and analyzing business data in order to optimize the efficiency of our sales and marketing efforts. In order to motivate our sales and marketing personnel, our commercial operation management center evaluates their performance periodically with reference to key performance indicators, and these evaluations are directly linked to their remuneration.

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## BUSINESS

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Our dedicated training department regularly provides in-house trainings to our sales and marketing personnel to enhance their knowledge about our products and professional skills. We also sponsor external training courses and programs for our sales and marketing personnel from time to time.

### *Academic Marketing*

We place strong emphasis on the academic marketing and promotion of our products. We organize, sponsor and participate in a wide variety of academic conferences, seminars and symposia, ranging from large-scale national and regional conferences to smaller local events tailored for specific hospital departments, to continuously enhance our brand recognition. For example, we have sponsored numerous academic conferences held by academic or professional associations such as the CSCO, the Chinese Medical Association Neurology Branch (中華醫學會神經內科分會), the Chinese Medical Association Neurosurgery Branch (中華醫學會神經外科分會) and the Chinese Medical Doctor Association (中國醫師協會).

We have established long-term relationships with a number of renowned physicians and other healthcare professionals in our target therapeutic areas. We consider these physicians and other healthcare professionals to be KOLs based on their professional qualifications, previous publications as well as academic standing and recognition within the relevant therapeutic area. We invite KOLs to attend national and regional conferences, share the latest industry developments and their experience in the relevant therapeutic areas.

In addition, our sales and marketing personnel visit healthcare professionals at our target hospitals and other medical institutions regularly to provide them with the most updated product information. We communicate with these healthcare professionals about the usage, clinical efficacy, safety and other features of our products and provide them with other product information such as the latest clinical research results and essays on the latest development of these products from well-known medical journals. We believe these hospital visits help assist the healthcare professionals in making independent evaluations of our products and alternative therapies in the market. Such visits also enable us to collect valuable feedback and market intelligence on our products, based on which we are able to continuously optimize our existing portfolio of products and to identify potential new products with unmet medical needs for commercialization.

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## BUSINESS

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### Third-party Promoters

To supplement our in-house sales and marketing capabilities, we engage third-party promoters to promote our products in medical institutions located in lower-tier cities or regions or that are otherwise not covered by our in-house sales and marketing team. We select third-party promoters based on their qualifications, reputation, marketing experience, management capabilities and hospital coverage. As of December 31, 2019, we had 116 third-party promoters.

We generally enter into annual promotion agreements with such third-party promoters, pursuant to which they are responsible for promoting our specified products in the designated geographic areas. Our third-party promoters are promotion service companies, the scope of whose services includes the promotion of our products to healthcare professionals by visiting hospitals and other medical institutions, disseminating product information, such as the mechanism of action and therapeutic benefits of our products, collecting market intelligence, as well as the formulation and implementation of annual promotion plans. Our third-party promoters typically receive service fees from us on a cost-plus basis. Pursuant to the annual promotion agreements, our third-party promoters are generally not allowed to promote any other products that compete with, or have any conflict of interest with, any of our products. Upon any breach of such non-competition undertaking by any third-party promoter, we may terminate the relevant agreement with such promoter and are entitled to claim damages from it. We require some of our third-party promoters to make performance deposits with us, which may be forfeited in the event of certain breaches of the promotion agreements, such as any breach of their non-competition undertaking. We also require our third-party promoters to strictly comply with the anti-bribery requirements in our promotion agreements.

### Distributors

We sell a substantial majority of our products to third-party distributors and depend on distributors for a substantial portion of our revenue. Our distributors are our direct customers, and are responsible for on-selling and delivering our products to hospitals, other medical institutions and pharmacies. Our distributors are not authorized by us to use our trade name or any other material which may lead others to believe that they are acting on our behalf.

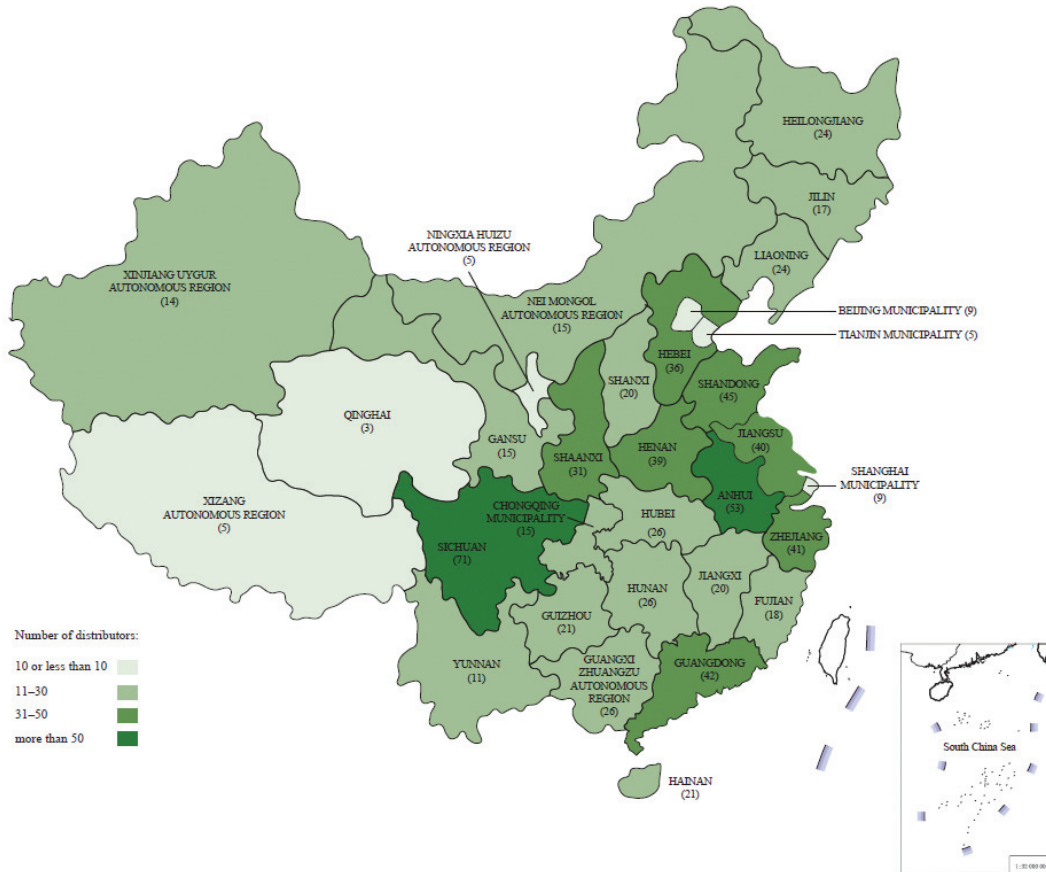
We benefit from our distributors’ established distribution channels and local resources to save costs that would otherwise be required to establish and maintain a nationwide logistics network across the PRC on our own, and to increase the effectiveness of launching and selling our products in our target markets within a short period of time. We believe our distributorship model is in line with industry norm.

As of December 31, 2019, our distribution network comprised 747 distributors spanning all 31 provinces, municipalities and autonomous regions across China. As of December 31, 2019, we also had three distributors for distribution in Taiwan, France and Lithuania, respectively. To the best knowledge of our Directors, during the Track Record Period, except Jiangsu Simcare Pharmaceutical, all of our distributors were Independent Third Parties, and

## BUSINESS

none of our distributors were wholly-owned or majority controlled by our current employees. In addition, to the best knowledge of our Directors, during the Track Record Period, none of our five largest distributors were wholly-owned or majority controlled by our ex-employees.

The following map illustrates the geographical coverage of our distributors in the PRC as of December 31, 2019:





## BUSINESS

The following table sets forth the movement of the number of our distributors for the periods indicated below:

	Year ended December 31,		
	2017	2018	2019
Number of distributors at the beginning of the period	492	722	827
Addition of new distributors	352	263	146
Termination of existing distributors	122	158	223
Net increase/(decrease) in distributors	<u>230</u>	<u>105</u>	<u>(77)</u>
<b>Number of distributors at the end of the period</b>	<b><u>722</u></b>	<b><u>827</u></b>	<b><u>750</u></b>

During the Track Record Period, our additions of new distributors primarily reflected (i) our continued sales growth, and (ii) for 2017 and 2018, our increasing coverage and penetration of county-level, community and rural hospitals and other medical institutions. Our terminations of distributors primarily reflected subpar performance, and an industry consolidation trend among distributors.

### *Terms of Distribution Agreements*

We enter into standardized distribution agreements with our distributors. Individual sales contracts are separately entered into for each purchase. Key terms of our distribution agreements include:

- **Term.** Typically one year.
- **Designated distribution area.** Distributors are not allowed to sell or distribute our products outside of their designated distribution areas.
- **Exclusivity.** Distributors are granted the distributorship of specified certain types of products in their designated distribution areas generally on a non-exclusive basis.
- **Sales target and minimum purchase requirement.** We set annual sales targets for our distributors. We do not grant any incentives or impose any penalties in connection with these sales targets. We do not stipulate any minimum purchase requirements for our distributors.
- **Pricing.** Our selling prices to distributors are fixed during the term of the distribution agreements. In the event of a retail price change as a result of regulatory or policy changes or centralized tender processes during the term of distribution agreement, we and the relevant distributor may negotiate price adjustments

## BUSINESS

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accordingly. 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. Please see “Risk Factors – Risks Relating to Our Business and Industry – 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.” We offer discounts to certain distributors in recognition of their compliance with the terms of the distribution agreements.

- ***Resale price management.*** We generally do not control the prices at which our distributors resell our products to their customers.
- ***Inventory level.*** Our distributors are required to maintain certain inventory levels to ensure the timely delivery of our products.
- ***Return of products.*** We generally do not allow product returns or exchanges except for defective products, which is subject to approval by our designated personnel from our quality control team. We generally do not accept the return of non-defective unsold or expired products.
- ***Access to information.*** Distributors are required to provide us with access to information at our request, including providing us with procurement, sales and inventory data of our products or with access to such information through their information technology system.
- ***Credit terms.*** We generally grant our distributors credit terms of 30 to 90 days, with longer terms granted to selected distributors with whom we have built a strong business and financial track record. We also require prepayments for product deliveries to our distributors in certain instances from a credit control perspective.
- ***Confidentiality.*** Both parties have non-disclosure obligations, and undertake to only use each other’s trade secrets and other business information to the extent necessary and not to disclose such trade secrets or other business information to any third party.
- ***Termination.*** We may terminate the distribution agreements in the event of (i) any material breach by our distributors, including, among others, sales outside of their designated distribution areas and providing falsified sales data; or (ii) any other breach by our distributors that is not remedied within a prescribed time-period.

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## BUSINESS

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We have a seller-buyer relationship with our distributors. We retain no ownership over the products that we sell to them, and all significant risks and rewards associated with these products are transferred to them upon delivery to and acceptance by them. Consequently, we recognize revenue from sales to our distributors upon delivery of our products to and acceptance by them. Our distributors on-sell our products to their customers, which do not have any contractual relationships with us and are not imposed with any of our control or oversight.

### *Distributor Management*

We select our distributors based on their proven distribution abilities, familiarity with their own target markets, financial strength, credit records and scale of operations. We require all our distributors to possess all licenses and permits necessary for the sales and distribution of pharmaceutical products. We require our distributors to adhere to the latest GSP standards for cold-chain storage and transportation so that they can deliver our products to covered medical institutions and pharmacies in a safe and timely manner.

Where a distributor breaches the relevant distribution agreement, including non-compliance with applicable laws and regulations, we will give the distributor a notice and require rectification. If no remedial action is taken within a prescribed time period, we will have the right to terminate the relevant distribution agreement.

We manage cannibalization risk among distributors through our agreements with our distributors, which specify the relevant products to be distributed and the designated geographical areas for which the distributor is responsible. The agreements also prohibit distributors from selling our products outside their respective designated geographical areas without our prior written consent. During the Track Record Period, we were not aware of any material cannibalization or competition among our distributors within the same geographical area.

The above procedures, combined with our product return policies, help ensure that our sales to distributors reflect genuine market demand and mitigate the risk of inventory accumulation in the distribution channels.

During the Track Record Period and up to the Latest Practicable Date, we did not provide financing to any of our distributors except for credit terms we granted to them under the relevant distribution agreements. There were no material product returns from our distributors during the Track Record Period. Please see “– Product Returns and Warranties” for more details.

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## BUSINESS

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### Direct Sales

To a lesser extent, we also sell our products and third-party products directly to large-scale national or regional pharmacy chains in China. We enter into standardized annual direct sales agreements with these pharmacy chains while individual sales contracts are separately entered into for each purchase. Pursuant to such annual direct sales agreements, our direct sales customer are required to purchase the designated products solely from us, and to sell such products in pharmacy stores operated by them or, with our written authorization, through online channels. We set annual sales targets for our direct sales customers but we do not grant any incentives or impose any penalties in connection with these sales targets. We offer discounts to our direct sales customers based on their total purchases from us. We are responsible for the delivery of our products to our direct sales customers at our own costs. Generally, we do not allow product returns or exchanges except for defective products, which is subject to approval by our designated personnel. Our direct sales customers are required to maintain a prescribed inventory level to ensure the timely delivery of our products. We typically grant our direct sales customers a credit term of 60 days and they pay us via wire transfer or bank acceptance bills. We may terminate the annual direct sales agreements in the event of (i) any material breach by our direct sales customers; or (ii) any other breach by pharmacy chains that is not remedied within a prescribed time-period.

### Logistics Arrangement

We generally use third-party logistics service providers to transport our products to our distributors and other direct customers in the PRC. We have entered into logistics service agreements with these providers, pursuant to which they are responsible for any loss caused by their negligence during the course of their logistics services, including transfer, loading, unloading, transportation and delivery to our customers.

### Distribution and Promotion of Third-party Pharmaceutical Products

In addition to our pharmaceutical products that we manufacture in-house, we market and/or sell third-party pharmaceutical products from reputable pharmaceutical companies, such as OLMETEC PLUS (olmesartan medoxomil and hydrochlorothiazide tablets) developed and manufactured by Daiichi Sankyo and Yingtaiqing-branded diclofenac sodium sustained-release capsules manufactured by CPU Pharma, which further enhances the breadth and competitive strength of our product portfolio in the relevant therapeutic areas. Due to the gradual implementation of the “dual invoicing system” across China from early 2017, currently we provide promotion services in respect of third-party pharmaceutical products distributed to medical institutions, while for third-party pharmaceutical products distributed to pharmacies, we sell and distribute these products to our distributors or directly to national or regional pharmacy chains. Please see “Regulatory Overview – Laws and Regulations Relating to Drugs – Dual Invoicing System” for more details about the “dual invoicing system.”

When we sell and distribute third-party pharmaceutical products, we purchase products from third-party pharmaceutical companies and earn a margin from on-selling and distributing such products to our distributors and national or regional pharmacy chains. We have entered into distribution agreements with such pharmaceutical companies with terms of up to 10 years, which have granted us the right to sell specified certain types of their products in China. We

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## BUSINESS

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are generally subject to annual minimum purchase and/or sales requirements specified in the distribution agreements. In the event that we fail to meet any such requirement, the relevant pharmaceutical company may be entitled to terminate the agreement with us, or seek compensation from us for the shortfall. Typically, we are required to make full prepayment, or are given 30 to 90 days’ credit terms, by such pharmaceutical companies. These pharmaceutical companies are generally responsible for arranging delivery of our purchases to locations designated by us, and we are generally entitled to return any defective products.

We provide promotion services to third-party pharmaceutical companies pursuant to promotion agreements with such pharmaceutical companies on an exclusive basis, or promotion clauses in our distribution agreements with such pharmaceutical companies, with terms of up to 10 years. Pursuant to the promotion agreements or clauses, we assist these pharmaceutical companies with the promotion of their products in China by, among others, introducing the relevant products to target customers and local authorities, as well as interacting with KOLs and healthcare professionals at the target medical institutions. We usually undertake annual minimum promotion requirements specified in the promotion agreements, and we achieve such requirements by procuring our distributors to purchase relevant products from such pharmaceutical companies. In return, we are generally entitled to receive promotion fees calculated as a percentage of our designated distributors’ total purchases based on the national average bidding prices of the relevant products. We generally grant such pharmaceutical companies credit terms of up to 90 days.

We are generally not allowed to produce, sell, distribute or promote competing products within the designated geographic areas. The agreements with these pharmaceutical companies may be terminated (i) by either party in the case of bankruptcy, insolvency or inability to pay due debts of the other party; (ii) by the non-defaulting party in the event of an irremediable material breach, or a material breach that is not remedied within a prescribed time period; (iii) by either party in the event of a change of control of the other party which makes it unable to perform its obligations under the agreements; or (iv) by the pharmaceutical companies if we fail to achieve the minimum purchase, sales and/or promotion requirements.

## PRODUCT RETURNS AND WARRANTIES

We generally do not accept any product returns, except for defective products. For defective products, we are fully responsible for the cost of return and replacement of these products. In respect of the return policy with our distributors, please see “– Sales, Marketing and Distribution – Distributors – Distributor Management” for the key terms of our distribution agreements.

We receive feedback from our distributors and end customers. We have dedicated personnel who take complaint calls and regularly review and analyze the feedback received. We treat such feedback and complaints seriously. We have implemented detailed procedures on how to handle quality complaints and provide for the contingency for any adverse patient reaction to our products. Our sales and marketing team is responsible for following up customer complaints to ensure that they have been dealt with appropriately.

## **BUSINESS**

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We did not provide any warranties on our products and did not have any provisions for warranty claims during the Track Record Period. During the Track Record Period and up to the Latest Practicable Date, the amounts of our product returns and exchanges were insignificant. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material complaint or product liability or other legal claims from our customers due to problems associated with the quality of our products.

We have also established product recall procedures with reference to relevant requirements, including GMP, and have prescribed recall guidelines and processes, which specify responsible persons to notify upon a recall and the handling procedure of the recalled products. During the Track Record Period and up to the Latest Practicable Date, we did not have any product recall due to quality problems.

### **PRICING**

#### **Centralized Tender Process**

A substantial portion of the products we sell to our distributors are then sold to public medical institutions in China. Public medical institutions at all levels are required to make substantially all of their purchases of pharmaceutical products through centralized tender processes. The centralized tender process is held in different provinces and cities across China with varying terms, procedures and preferences and is usually organized at the national, provincial or city levels. How often a drug is required to resubmit a tender under the centralized tender process varies across different provinces, which is generally not less than 12 months. See “Regulatory Overview – Tender Process” for further details of the tender process in the PRC. The selection of the winning bidder is based on a number of criteria, including bid price, product quality, clinical effectiveness, as well as qualifications and reputation of the manufacturer. The successful bid price in the centralized tender process dictates the price at which distributors sell the relevant product to the relevant public medical institutions. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public medical institutions in the designated regions at the bid prices, which in part determine the prices at which we sell our products to our distributors. The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. During the Track Record Period, the prices of some of our major products decreased primarily due to downward pricing pressure from the centralized tender process in several provinces which required 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 bidding strategy generally focuses on differentiating our products instead of competing solely based on pricing.

We have formulated detailed policies and processes in coping with competition in different provinces’ centralized tender processes, with the goal of maintaining the price levels of our products and maximizing our overall sales. In particular, our internal sales and marketing team actively communicates with the local authorities in charge of the centralized tender process and promptly notifies us of any tendering proposals. Our strategic account department studies the tendering proposals, including the minimum bid requirements, if any, and pricing trends for each dosage form of our products and of our competitor products on a province-by-province basis to form a bid. Our strategic account department also closely

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## BUSINESS

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monitors new policies affecting the pricing of pharmaceutical products in China and formulate strategies to stay competitive and profitable. For example, during the Track Record Period, each of our major products that participated in the centralized tender processes received certain preferential treatment varying across different provinces, because (i) the product was an innovative or first-to-market generic pharmaceutical; (ii) we or the product had received national-level recognition, including being named in the Top 100 Pharmaceutical Manufacturing Enterprise in China (中國醫藥工業百強企業); or (iii) the product had passed the quality and efficacy consistency evaluation.

### **Pricing Regulation Affecting Our Major Products**

Prior to June 1, 2015, pharmaceutical products were subject to price controls mainly in the form of maximum retail prices at which pharmaceutical products may be sold to patients through medical institutions and pharmacies. In May 2015, NDRC, NHFPC, MOHRSS, MIIT, MOF, MOFCOM and CFDA jointly promulgated the “Notice Regarding the Opinions on Facilitating Pharmaceutical Pricing Reform” (《關於印發推進藥品價格改革意見的通知》), pursuant to which, with the exception of narcotic and Class I psychotropic drugs, government price controls on pharmaceutical products were lifted starting from June 1, 2015, allowing for a more market-based drug pricing system. Instead of direct price controls, the PRC government continued to regulate drug pricing mainly through a centralized tender process, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices. This notice also reiterates the policy of establishing a transparent, multi-party negotiation mechanism for the pricing of patented and exclusive drugs. See “Regulatory Overview – Price Controls” for more details.

Despite the regulatory change, certain new regulations could still exert downward pressure on drug pricing from participation in the centralized tender process and, if significant, could have a corresponding impact on the prices at which we sell our pharmaceutical products, and consequently our profit margin. For example, the PRC government launched the national scheme for centralized drug tendering with minimum procurement quantities in November 2018, which is aimed at reducing drug prices. Please see “Regulatory Overview – The Drug Centralized Procurement in “4+7 Cities” and Wider Areas” for more details. This newly implemented program has resulted in increased pricing pressure on us. Please see “Risk Factors – Risks Relating to Our Business and Industry – 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” for further details of risks associated with pricing regulation.

In addition, innovative pharmaceuticals included in any national medical insurance negotiation list generally need to undergo a 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.



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## BUSINESS

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During the Track Record Period, we determined our selling prices to our distributors or other direct customers after taking into account factors such as (i) the successful bid prices with hospitals and other medical institutions, if applicable; (ii) our production costs; (iii) the pricing of competing products; and (iv) an acceptable level of profit margin for both ourselves and our distributors, if applicable. During the Track Record Period, neither the centralized tender process nor the pricing regulations discussed above had any material adverse effect on our business or results of operations as the increases in sales volume offset the price declines, and as we had a diverse product portfolio and did not rely on any single product, and strategically structured our product portfolio to focus on innovative products which had higher profit margins.

### OUR CUSTOMERS AND SUPPLIERS

#### Our Customers

Our customers primarily consist of (i) our distributors and pharmacy chains which directly purchase pharmaceutical products from us; and (ii) other pharmaceutical manufacturers to which we provide promotion services.

For the years ended December 31, 2017, 2018 and 2019, sales to our five largest customers collectively accounted for approximately 14.0%, 12.8% and 9.9% of our total revenue during the same periods, respectively, and purchases from our largest customer accounted for approximately 5.4%, 5.4% and 2.6% of our total revenue during the same periods, respectively. Our five largest customers during the Track Record Period comprise our distributors. All of our five largest customers during the Track Record Period are Independent Third Parties. We have had relationships with our five largest customers for over 10 years as of the Latest Practicable Date. To the best of the knowledge of our Directors, none of our Directors, their respective associates or any shareholder who owns more than 5% of our issued share capital had any interest in any of our five largest customers during the Track Record Period.

#### Our Suppliers

Our suppliers primarily include (i) suppliers for the raw materials of our pharmaceutical products; and (ii) manufacturers of third-party pharmaceutical products.

For the years ended December 31, 2017, 2018 and 2019, purchases from our five largest suppliers collectively accounted for approximately 42.5%, 42.7% and 39.4% of our total purchases during the same periods, respectively, and purchases from our largest supplier accounted for approximately 14.6%, 19.0% and 15.7% of our total purchases during the same periods, respectively. Our five largest suppliers during the Track Record Period comprise raw material suppliers and manufacturers of third-party pharmaceutical products. All of our five largest suppliers during the Track Record Period are Independent Third Parties. We have had relationships with our five largest suppliers for four to 20 years as of the Latest Practicable Date. To the best of the knowledge of our Directors, none of our Directors, their respective associates or any shareholder who owns more than 5% of our issued share capital had any interest in any of our five largest suppliers during the Track Record Period.

## BUSINESS

### AWARDS AND RECOGNITIONS

The following table sets forth our recent major awards and recognitions (other than those disclosed in “– Our Existing Product Portfolio”):

Year	Entity Receiving Award	Award	Award Issuing Authority
2020	Jiangsu Simcere	2020 National Demonstration Base for Talents Introduction (2020年度國家引才引智示範基地)	Ministry of Science and Technology of the PRC (中華人民共和國科學技術部)
2019	Jiangsu Simcere	Jiangsu Foreign Expert Workshop (江蘇省外國專家工作室)	Jiangsu Provincial Science and Technology Department (江蘇省科學技術廳)
2019	Simcere Dongyuan	2019 Innovative Pharmaceutical Enterprise in China (2019年中國創新力醫藥企業)	China State Institute of Pharmaceutical Industry (中國醫藥工業研究總院)
2019	Simcere Dongyuan	2018 Top 100 Pharmaceutical Manufacturing Enterprise in China (2018年中國醫藥工業百強企業)	China National Pharmaceutical Industry Information Center of MIIT (中華人民共和國工業和信息化部中國醫藥工業信息中心)
2018	Jiangsu Simcere	2018 to 2021 National Intellectual Property Demonstration Enterprise (2018年至2021年國家知識產權示範企業)	National Intellectual Property Administration of the PRC (中華人民共和國知識產權局)
2017	Jiangsu Simcere	2017 Pilot Enterprise of Mass Entrepreneurship and Mass Innovation Platform in Manufacturing Industry (2017年製造業「雙創」平台試點示範企業)	MIIT

## BUSINESS

Year	Entity Receiving Award	Award	Award Issuing Authority
2017	Jiangsu Simcere	National Specialized Innovation Space (國家專業化眾創空間)	Ministry of Science and Technology of the PRC (中華人民共和國科學技術部)
2014 to 2018	Hainan Simcere	2014 to 2018 Innovative Pharmaceutical Enterprise in China (2014年至2018年中國創新力醫藥企業)	China State Institute of Pharmaceutical Industry (中國醫藥工業研究總院)
2013	Jiangsu Simcere	International Science and Technology Cooperation Base (國際科技合作基地)	Ministry of Science and Technology of the PRC (中華人民共和國科學技術部)
2012 to 2014; 2016 to 2019	Hainan Simcere	2012 to 2014 and 2016 to 2019 Top Manufacturing Enterprise for Pharmaceutical R&D Product Line in China (2012年至2014年及2016年至2019年中國醫藥研發產品線最佳工業企業)	China National Pharmaceutical Industry Information Center of MIIT (中華人民共和國工業和信息化部中國醫藥工業信息中心)
2010 to 2018	Hainan Simcere	2009 to 2017 Top 100 Pharmaceutical Manufacturing Enterprise in China (2009年至2017年中國醫藥工業百強企業)	China National Pharmaceutical Industry Information Center of MIIT (中華人民共和國工業和信息化部中國醫藥工業信息中心)

## INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we had (i) 216 registered patents and 61 pending patent applications in the PRC; (ii) 21 patents and four pending patent applications overseas; and (iii) six registered domain names in the PRC. As of the Latest Practicable Date, we had 71 registered trademarks in the PRC and seven registered trademarks overseas, which we consider to be or may be material to our business. Details of our intellectual property rights are set forth under the section headed “Appendix IV – Statutory and General Information – B. Further Information about Our Business – 2. Intellectual Property Rights of Our Group” in this document.

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## BUSINESS

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We rely on intellectual property rights to protect our technologies, inventions and improvements that we believe are important to maintain the market share of our products. A substantial portion of our products have intellectual property rights relating principally to their compound, compositions, preparation methods and/or production processes. See “– Our Product Portfolio – Our Existing Product Portfolio” for further details of the intellectual property rights for our major products.

In order to protect our intellectual property rights, we generally require our employees to enter into confidentiality agreements. These agreements typically provide that all relevant intellectual properties developed by our employees during the course of their employment with us become our intellectual properties and are treated as trade secrets. Our employees are contractually required to refrain from disclosing confidential information to third parties unless authorized in writing by our Board. We also follow procedures, such as patent searches, to ensure that we do not infringe on the intellectual property rights of others and are not engaged in the sale of counterfeit pharmaceutical products.

During the Track Record Period and up to the Latest Practicable Date, save as otherwise disclosed in this document, we had not been sued on the basis of, and had not undergone arbitration in respect of, nor had we received any notification from third parties claiming infringement of any intellectual property or sales of counterfeit pharmaceutical products that have had a material adverse effect on our business. In addition, during the Track Record Period and up to the Latest Practicable Date, we had not been the subject of any adverse finding in an investigation or audit by any governmental authorities in respect of the infringement of any intellectual property of third parties or sales of counterfeit pharmaceutical products that had a material adverse effect on our business. However, despite our internal control procedures, we are still subject to risks relating to intellectual property rights. See “Risk Factors – Risks Relating to Our Business and Industry – 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” and “Risk Factors – Risks Relating to Our Business and Industry – 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.”

## COMPETITION

The pharmaceutical market in China is highly competitive and is characterized by a number of established pharmaceutical companies, as well as some emerging biotechnology companies. We face competition from other pharmaceutical companies and emerging biotechnology companies engaged in the research, development, production, marketing or sales of pharmaceutical products. 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.

## BUSINESS

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. The identities of our key competitors vary by product and, in certain cases, our competitors may have greater financial and research and development resources than us, may elect to focus these resources on developing, importing or in-licensing and marketing products in China that are substitutes for our products and may have broader sales and marketing infrastructure with which to do so. Please see “Industry Overview” for more details about the major competitors of our products.

We believe our continued success will depend on our following capabilities: the capability to develop innovative products and advanced technologies; the capability to apply technologies to all production lines; the capability to develop an extensive product portfolio; the capability to maintain a highly efficient operational model; the capability to attract, retain and cultivate talent; the capability to maintain high quality standards; the capability to obtain and maintain regulatory approvals; and the capability to effectively market and promote products.

## EMPLOYEES

As of December 31, 2019, we had 4,966 full-time employees, including 4,914 in China, two in Hong Kong, 45 in the United States and five in Great Britain. The following table provides a breakdown of our employees by department function as of that date:

Department Function	Number of employees	% of total employees
Research and development	699	14.1
Manufacturing	1,360	27.4
Sales and marketing	2,638	53.1
Others (including operational and management)	269	5.4
<b>Total</b>	<b>4,966</b>	<b>100.0</b>

We believe we have maintained good relationships with our employees. Our employees do not negotiate their terms of employment through any labor union or by way of collective bargaining agreements. As of the Latest Practicable Date, we did not experience any strikes or any labor disputes with our employees which have had or are likely to have a material effect on our business.

Our employees typically enter into standard employment contracts with us. We place high value on recruiting, training and retaining qualified employees. We maintain high standards on selecting and recruiting talent worldwide and provide competitive compensation packages. Remuneration packages for our employees mainly comprise base salary and performance-based bonus. To maintain and enhance the quality, knowledge and skill levels of our workforce as

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## BUSINESS

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well as their familiarity with industry quality standards and work safety standards, through Sincere Institute, our in-house training department, we provide our employees with periodic training, including orientation programs for new employees, technical training, professional and management training and health and safety training. We also provide our sales and marketing team with extensive training. See “– Sales, Marketing and Distribution – In-house Sales and Marketing Team” for more details.

We set performance targets for our employees primarily based on their position and department and periodically review their performance. The results of such reviews are used in their salary determinations, bonus awards and promotion appraisals. We also align our interest with those of our management team and selected employees by offering them participation in the [REDACTED] Share Incentive Scheme. Please see “Appendix IV – Statutory and General Information – D. [REDACTED] Share Incentive Scheme.”

We contribute to social security insurance and housing provident funds for our employees in accordance with applicable PRC laws, rules and regulations.

## LAND AND PROPERTIES

As of the Latest Practicable Date, we owned 37 properties in the PRC ranging from a GFA of approximately 13.52 sq.m. to approximately 71,746.04 sq.m., with a total GFA of approximately 140,515.56 sq.m. Our owned properties are located at Haikou, Nanjing, Beijing, Shanghai, Wuhu and Yantai and are primarily used as production facilities, ancillary facilities, offices, laboratories, employee dormitories, canteens and car parking spaces. We hold land use rights for 12 parcels of land for industrial and residential use ranging from a site area of approximately 13.52 sq.m. to approximately 259,371.08 sq.m., with a total site area of approximately 726,873.69 sq.m. on which our owned properties are constructed. As of Latest Practicable Date, seven of our owned properties with a total GFA of approximately 28,593.74 sq.m. and one parcel of land that we held land use rights with a total site area of approximately 152,187.58 sq.m. were pledged to CDB Development Fund to guarantee our performance of investment return obligations under the Investment Agreement. We are currently in the process of completing the relevant pledge registration procedures. Please see “History, Reorganization and Corporate Structure – Reorganization – Onshore Reorganization – Shareholding Changes in Hainan Sincere – Investment by CDB Development Fund” for more details. In addition, one of our owned properties with a GFA of approximately 71,746.04 sq.m. and one parcel of land that we held land use rights with a site area of approximately 35,549.00 sq.m. were pledged to secure our bank borrowings. Save as disclosed above, none of our owned properties and land that we held land use rights for were subject to any encumbrance, mortgage, lien or pledge as of the Latest Practicable Date.

We are in the process of obtaining the building ownership certificate for one property with a GFA of 949.61 sq.m., representing approximately 0.7% of the total GFA of the properties that we owned as of the Latest Practicable Date. Based on written confirmation we received from the Wuhu Sanshan Economic Development Management Committee (蕪湖三山經濟開發區管理委員會), which is the competent authority as advised by our PRC Legal Advisors, our PRC

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## BUSINESS

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Legal Advisors have advised us that we currently have the ownership of such property and we will not be subject to any material legal impediment in obtaining the building ownership certificate for such property. We expect to obtain the building ownership certificate for such property in the third quarter of 2020. Except for the abovementioned property, we have obtained the building ownership certificates and the related land use right certificates for all of our 37 owned properties as of the Latest Practicable Date.

As of the Latest Practicable Date, we leased 38 properties in Nanjing, Suzhou, Zigong, Beijing, Hong Kong, the United States and the United Kingdom with a total GFA of approximately 39,658.55 sq.m. (excluding the GFA of three properties, which were dorm rooms leased for our employees). Our leased properties are primarily used as offices, employee dormitories, warehouses and laboratories. As of the Latest Practicable Date, we leased four parcels of land in Zigong with a total site area of approximately 2,680.00 sq.m., which were primarily used for bentonite mining.

As of December 31, 2019, 18,639.94 sq.m. of our owned properties were rented out to certain Independent Third Parties. The carrying amounts of our interest in such properties accounted for less than 1% of our total assets as of December 31, 2019. According to Chapter 5 of the Listing Rules and Section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 38(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to all of our interests in land and buildings, because as of December 31, 2019, we had no single property interest with a carrying amount of 15% or more of our total assets.

As of the Latest Practicable Date, 32 of our lease agreements with an aggregate GFA of approximately 36,793.55 sq.m. and the lease agreements of three properties, which were dorm rooms leased for our employees, had not been registered with the relevant PRC authorities, primarily due to difficulties in procuring our lessors' cooperation. As advised by our PRC Legal Advisors, failure to register an executed lease agreement will not affect its legality, validity or enforceability. However, we may be subject to a fine of no less than RMB1,000 and not exceeding RMB10,000 for each unregistered lease agreement if the relevant PRC government authorities require us to rectify and we fail to do so within the prescribed time period. We estimate that the maximum penalty we may be subject to for these unregistered lease agreements will be approximately RMB350,000, which we believe is immaterial. Therefore, we believe that the failure to register these lease agreements will not have any material adverse effect on our financial condition or results of operations. We will actively liaise with the respective lessors to complete the registration of all such lease agreements, if possible.



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## BUSINESS

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### INSURANCE

We maintain property insurance covering physical damage to, or loss of, our facilities, equipment, office furniture and inventory; employer’s liability insurance covering death or work injury of employees; and clinical trial insurance covering us against liability in the event of injury to any trial subject caused by serious adverse events in our clinical trials. We are not required under PRC laws and regulations to, and we generally do not, purchase any product liability insurance or key person insurance. We contribute to social security insurance for our employees in accordance with applicable PRC laws, rules and regulations.

During the Track Record Period and up to the Latest Practicable Date, we did not submit any material insurance claims, nor did we experience any material difficulties in renewing our insurance policies.

Our Directors believe that our insurance coverage is adequate and in line with industry norm. However, the risks related to our business and operations may not be fully covered by insurance. Please see “Risk Factors – Risks Relating to Our Business and Industry – Our insurance coverage is limited; if we experience uninsured losses, it could adversely affect our financial condition and results of operations.”

### HEALTH, OCCUPATIONAL SAFETY AND ENVIRONMENTAL PROTECTION

#### Health and Occupational Safety

We are subject to various PRC laws and regulations in respect of health and occupational safety. We are committed to complying with PRC regulatory requirements, preventing and reducing hazards and risks associated with our operation, and ensuring the health and safety of our employees and surrounding communities. We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees, including those required under the GMP certification. For example, we require new employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In addition, we conduct on-site safety assessment and hazard identification, which help us enhance our overall health and safety management effectiveness. We have a system in place for recording and handling accidents. We have designated personnel responsible for handling work accidents and injuries as well as maintaining health and work safety compliance record. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material accidents in the course of our operations, nor were we subject to any material claims for personal or property damages in connection with health and occupational safety.

## BUSINESS

### Environmental Protection

The main pollutants generated during our production process includes waste water, waste gas and solid wastes, which include general solid wastes and hazardous solid wastes. We have implemented pollution control measures in order to comply with applicable laws and regulations. We have a sewage treatment system in our production facilities. After processing, our waste water is safely discharged into the downstream sewage treatment facilities or municipal sewer network. We have also installed dust removers in our production facilities (excluding our Wuhu facility) to purify the collected waste gas before emission. In addition, we have engaged qualified sanitation companies or hazardous waste treatment companies for treatment of solid wastes generated during the production process. We believe that we have adopted effective anti-pollution measures and that we are in compliance in all material respects with applicable environmental laws and regulations during the Track Record Period. For each of the years ended December 31, 2017, 2018 and 2019, our costs for compliance with the applicable environmental rules and regulations as a percentage of total revenue for the same periods remained less than 0.5%. We do not expect there to be substantial changes to our costs for compliance with the applicable environmental rules and regulations in the near future.

### LICENSES, PERMITS AND CERTIFICATES

As advised by our PRC Legal Advisors, we had obtained all material licenses, permits and approvals required for our operations in the PRC and such licenses, permits and approvals were valid and remain in effect as of the Latest Practicable Date. The following table sets forth the major licenses, permits and certificates for our business operations as of the Latest Practicable Date (apart from those pertaining to general business requirements):

License/Permit/ Certificate	Holder	Purpose	Issuing Authority	Validity Period
Drug Production License (藥品生產許可證) (瓊20150035)	Hainan Simcere	Production of pharmaceutical products at our Yaogu facility and Chengmai facility	Hainan Provincial Drug Administration (海南省藥品監督管理局, formerly known as Hainan Provincial Food and Drug Administration (海南省食品藥品監督管理局)) (“Hainan DA”)	December 30, 2015 – December 29, 2020
Drug Production License (藥品生產許可證) (蘇20160001)	Simcere Dongyuan	Production of pharmaceutical products at our Nanjing facility	Jiangsu Provincial Drug Administration (江蘇省藥品監督管理局, formerly known as Jiangsu Provincial Food and Drug Administration (江蘇省食品藥品監督管理局)) (“Jiangsu DA”)	October 15, 2019 – December 31, 2020

## BUSINESS

License/Permit/ Certificate	Holder	Purpose	Issuing Authority	Validity Period
Drug Production License (藥品生產許可證) (魯20160101)	Shandong Sincere	Production of bioengineering products at our Yantai facility	Shandong Provincial Medical Products Administration (山東省藥 品監督管理局, formerly known as Shandong Provincial Food and Medical Products Administration (山東省食 品藥品監督管理局)) (“Shandong MPA”)	January 1, 2016 – December 31, 2020
Drug Production License (藥品生產許可證) (皖20160201)	Wuhu Sincere	Production of antineoplastic implants at our Wuhu facility	Anhui Medical Products Administration (安徽省藥 品監督管理局, formerly known as Anhui Provincial Food and Medical Products Administration (安徽省食 品藥品監督管理局)) (“Anhui MPA”)	January 1, 2016 – December 31, 2020
Pharmaceutical Operation Permit (藥品經營許可證) (蘇AA0250009)	Jiangsu Sincere	Wholesale of pharmaceutical products	Jiangsu DA	November 12, 2019 – November 11, 2024
Pharmaceutical Operation Permit (藥品經營許可證) (滬AA0210054)	Shanghai Sincere	Wholesale of pharmaceutical products	Shanghai Drug Administration (上海市藥 品監督管理局, formerly known as Shanghai Food and Drug Administration (上海市食品藥品監督管理 局)) (“Shanghai DA”)	March 27, 2019 – January 24, 2022
GMP (HI20160012)	Hainan Sincere	Production of cephalosporin oral suspensions, granules and hard capsules, and production of penicillin oral suspensions, tablets, granules and hard capsules, at our Chengmai facility	Hainan DA	August 8, 2016 – August 7, 2021

## BUSINESS

License/Permit/ Certificate	Holder	Purpose	Issuing Authority	Validity Period
GMP (HI20160016)	Hainan Simcere	Production of tablets, hard capsules, granules, powders and gel at our Yaogu facility	Hainan DA	September 26, 2016 – September 25, 2021
GMP (HI20190019)	Hainan Simcere	Production of API (diosmectite) at our Yaogu facility	Hainan DA	April 17, 2019 – April 16, 2024
Certificate of GMP Compliance of a Manufacturer (6015/06.08.02.00/2016)	Hainan Simcere	Production of diosmectite powder (for EU exportation) at our Yaogu facility	Finnish Medicines Agency	May 10, 2019 – May 09, 2022
Qualified Person’s Declaration on GMP Compliance (EMA/334808/2014)	Hainan Simcere	Production of API (diosmectite) used for the production of diosmectite (for EU exportation) at our Yaogu facility	European Medicines Agency	August 29, 2019 – August 28, 2022
GMP (JS20180783)	Simcere Dongyuan	Production of oral liquid and extraction of Chinese medicine at our Nanjing facility	Jiangsu DA	March 5, 2018 – March 4, 2023
GMP (JS20180815)	Simcere Dongyuan	Production of small volume injectable solutions at our Nanjing facility	Jiangsu DA	April 17, 2018 – April 16, 2023
GMP (JS20180909)	Simcere Dongyuan	Production of hard capsules, powder aerosols and APIs (nedaplatin and pemetrexed disodium) at our Nanjing facility	Jiangsu DA	October 15, 2018 – October 14, 2023
GMP (JS20180927)	Simcere Dongyuan	Production of API (zanamivir) at our Nanjing facility	Jiangsu DA	November 23, 2018 – November 22, 2023

## BUSINESS

License/Permit/ Certificate	Holder	Purpose	Issuing Authority	Validity Period
GMP (JS20191044)	Simcere Dongyuan	Production of antineoplastic lyophilized powder for injection, aseptic API (biapenem), powder for injection and API (palonosetron hydrochloride) at our Nanjing facility	Jiangsu DA	May 5, 2019 – May 4, 2024
GMP (JS20191135)	Simcere Dongyuan	Production of tablets and API (oxaliplatin) at our Nanjing facility	Jiangsu DA	August 30, 2019 – August 29, 2024
GMP (JS20191158)	Simcere Dongyuan	Production of APIs (bortezomib and pramipexole dihydrochloride) at our Nanjing facility	Jiangsu DA	October 12, 2019 – October 11, 2024
GMP (SD201800740)	Shandong Simcere	Production of recombinant human endostatin injection at our Yantai facility	Shandong MPA	July 26, 2018 – July 25, 2023
GMP (AH20180449)	Wuhu Simcere	Production of antineoplastic implants at our Wuhu facility	Anhui MPA	April 8, 2018 – April 7, 2023
Certificate of GSP for Pharmaceutical Products (藥品 GSP證書) (A-JS20-001)	Jiangsu Simcere	Wholesale of pharmaceutical products	Jiangsu DA	January 7, 2020 – January 7, 2025
Certificate of GSP for Pharmaceutical Products (藥品 GSP證書) (A-SH17-002)	Shanghai Simcere	Wholesale of pharmaceutical products	Shanghai DA	April 21, 2019 – January 24, 2022
Mining Permit (採礦許可證) (C51030020101 27120093239)	Zigong Yirong	Exploration of bentonite	Bureau of Land and Resources of Zigong (自貢市國土資源局)	August 3, 2019 – October 3, 2022

## BUSINESS

License/Permit/ Certificate	Holder	Purpose	Issuing Authority	Validity Period
Production Safety License (安全生產許可證) ((川)C)FM 安許證字 [2018]003)	Zigong Yirong	Exploration of bentonite	Administration of Work Safety of Zigong (自貢市安全生產監督管理局)	June 23, 2018 – June 22, 2021

We monitor the validity status of, and make timely applications for the renewal of, relevant licenses, permits and certificates prior to the expiration date. We had not experienced any material difficulty in obtaining or renewing the required licenses, permits and certificates for our business operations during the Track Record Period and up to the Latest Practicable Date. Our PRC Legal Advisors are of the view that, there is no material legal impediment in renewing these licenses, permits, approvals and certificates as they expire in future as long as we are in compliance with applicable laws, regulations and rules. See “Risk Factors – Risks Relating to Our Business and Industry – 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.”

## LEGAL PROCEEDINGS AND COMPLIANCE

### Compliance

During the Track Record Period and up to the Latest Practicable Date, we did not have any non-compliance incidents which our Directors believe would, individually or in aggregate, have a material adverse operational or financial impact on our Group as a whole.

### Legal Proceedings

We are subject to legal proceedings, disputes and claims that arise in the ordinary course of business. As of the Latest Practicable Date, we were not a party to any ongoing material litigation, arbitration or administrative proceedings, and we are not aware of any claims or proceedings contemplated by government authorities or third parties which would materially and adversely affect our business. Our Directors are not involved in any actual or threatened material claims or litigation.

We are currently involved in a trademark litigation brought by CPU Pharma in 2018, requesting us to transfer 50% of ownership to the Yingtaiqing trademark to CPU Pharma in accordance with an agreement entered into in 1998 (the “**1998 Agreement**”). During the first trial, the court dismissed all CPU Pharma’s claims against us on the grounds that CPU Pharma is not entitled to claim specific performance based on the 1998 Agreement. CPU Pharma subsequently appealed, and the court has yet to reach a decision in respect of the appeal. We

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## BUSINESS

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do not consider it a material legal proceeding, and the litigation and its outcome do not affect our distribution of Yingtaiqing-branded capsules manufactured by CPU Pharma, nor our manufacturing and sales of Yingtaiqing-branded gel.

### INTERNAL CONTROL AND RISK MANAGEMENT

It is the responsibility of our Board to ensure that we maintain sound and effective internal controls to safeguard our Shareholders’ investment and our assets at all times. We have adopted, or expect to adopt before the [REDACTED], a series of internal control policies, procedures and programs designed to provide reasonable assurance for achieving objectives, including effective and efficient operations, reliable financial reporting and compliance with applicable laws and regulations.

In particular, we have established a code of conduct and ethics governing commercial transactions (the “**Code of Conduct**”) since 2007. Specifically, the Code of Conduct prescribes that providing or accepting appropriate gifts and hospitalities are customary business practices which are considered business etiquette during the establishment of relationships with our business partners, to the extent that such gifts and hospitalities will not affect or appear to affect the fairness of commercial decisions. Employees are only allowed to accept appropriate gifts and are required to turn in any gift received which is worth more than RMB200 to our compliance department. All political contributions, whether directly or through professional associations, are strictly prohibited unless otherwise approved by our chief executive officer or chief financial officer. In addition, the Code of Conduct strictly prohibits (i) provision or acceptance of kickbacks, bribes or other improper gains or benefits by our employees; (ii) knowingly dissemination of false information in respect of our competitors, customers or suppliers; (iii) willful misstatements of information regarding the quality and nature of our products; or (iv) advancing our business interests through unfair competition, either directly or indirectly. Our employees are required to sign a declaration at the end of the Code of Conduct confirming that they have received, read and understood the Code of Conduct and undertake their compliance with the Code of Conduct requirements. Employees who violate the Code of Conduct are subject to penalties, including termination of employment.

To further enhance our anti-bribery and anti-corruption practice, we newly adopted a set of internal policies against bribery and corrupt activities (the “**Internal Anti-bribery Policies**”) in January 2019, which strictly prohibit all employees and other personnel acting on behalf of us from making, proposing or promising improper payments, directly or indirectly, in any form of cash, physical assets, loans, gifts, luxury trips, entertainments, donations, other valuables or benefits to anyone, including government officers and healthcare professionals, for the purposes of acquiring or securing any business or improper advantage, regardless of whether we benefit from such improper payments. Specifically, all employees are prohibited from (i) the offer of cash or cash equivalents to government officers and healthcare professionals; (ii) the offer of personal gifts (except for small amounts of gifts in accordance with customary business practice) to government officers and healthcare professionals; (iii) sponsoring conferences with the attendance of government officers and healthcare professionals which are not held for the purpose of introducing our products or providing



## BUSINESS

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scientific or educational information; (iv) reimbursement of travel and accommodation expenses for accompanying guests and relatives of government officers and healthcare professionals; (v) compensating government officers and healthcare professionals only for their attendance of conferences; and (vi) the offer of entertainment or leisure activities to government officers and healthcare professionals (other than conference-related accommodation). In connection with sponsorship of conferences and academic marketing activities, the Internal Anti-bribery Policies prohibit extravagant spending on food, catering and hospitality, unless a prior written approval of our chief compliance officer is obtained. The Internal Anti-bribery Policies require the use of accurate, objective and complete information with supporting sources in promotion activities related to our products. Presentation materials related to promotion activities are required to be reviewed internally. All product samples provided to healthcare professionals are required to be clearly labelled to prevent potential misuse. All charitable donations are required to be made in accordance with the Internal Anti-bribery Policies. The Internal Anti-bribery Policies strictly prohibit facilitation payments, regardless of its legality in the relevant jurisdictions. Employees who violate the Internal Anti-bribery Policies are subject to penalties, including termination of employment. We have also specified anti-bribery requirements in our contractual agreements with our business partners, including distributors and third-party promoters. In addition, we require our employees as well as our business partners to sign anti-bribery undertakings on an annual basis. The Internal Anti-bribery Policies also include whistleblower provisions that require all employees to report any suspected non-compliance, which will be submitted to our chief compliance officer or the chairman of our Audit Committee.

We have formed the Audit Committee comprising three independent non-executive Directors as part of our measures to improve corporate governance. The primary duties of the audit committee are to provide our Directors with an independent review of the effectiveness of our financial reporting process, internal control and risk management system, to oversee the audit process and to perform other duties and responsibilities as assigned by our Directors. Please see “Directors and Senior Management” for details about the members of our audit committee and the Board. We plan to continue strengthening our risk management policies, including anti-bribery compliances, by ensuring regular management review of relevant corporate governance measures and the implementation by each subsidiary and each corresponding department.