Simcere Pharmaceutical Group
Form 20-F
June 18, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

o **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-33398

Simcere Pharmaceutical Group

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant s name into English)

Cayman Islands

(Jurisdiction of incorporation or organization)

No. 699-18 Xuan Wu Avenue,
Xuan Wu District, Nanjing
Jiangsu Province 210042
People s Republic of China

(Address of principal executive offices)

Zhigang Zhao
Chief Financial Officer
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(Name, telephone, e-mail and/or facsimile number and address of company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of Each Securities	Name of Each Exchange on Which Registered
American Depositary Shares, each representing two ordinary shares, par value $0.01 per share	**New York Stock Exchange**

Securities registered or to be registered pursuant to Section 12(g) of the Act:
None

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:
None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report. 122,227,318 ordinary shares, par value $0.01 per share.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes o No þ

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer o Accelerated filer þ Non-accelerated filer o

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP þ

International Financial Reporting Standards as issued by the International Accounting Standards Board o

Other o

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 o Item 18 o

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes o No o

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INTRODUCTION

Unless otherwise indicated, references in this annual report on Form 20-F to:

$ and U.S. dollars refer to the legal currency of the United States;

ADRs refer to the American depositary receipts, which, if issued, evidence our ADSs;

ADSs refer to our American depositary shares, each of which represents two ordinary shares;

China and the PRC refer to the People s Republic of China, excluding, for the purpose of this annual report on Form 20-F only, Taiwan and the special administrative regions of Hong Kong and Macau;

ordinary shares refer to our ordinary shares, par value $0.01 per share;

RMB and Renminbi refer to the legal currency of China; and

we, us, our company and our refer to Simcere Pharmaceutical Group, its predecessor entities and its consolidated subsidiaries.

This annual report on Form 20-F includes our audited consolidated financial statements for the years ended December 31, 2006, 2007 and 2008.

We and certain selling shareholders of our company completed the initial public offering of 15,625,000 ADSs, each representing two ordinary shares, in April 2007. On April 20, 2007, we listed our ADSs on the New York Stock Exchange under the symbol SCR.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not Applicable.

Item 2. Offer Statistics And Expected Timetable

Not Applicable.

Item 3. Key Information

A. Selected Financial Data

The selected data presented below under the captions Selected Consolidated Statement of Income data (other than ADS data) and Selected Consolidated Balance Sheet Data for, and as of the end of, each of the years in the five-year period ended December 31, 2008, are derived from our consolidated financial statements and related notes thereto. Our consolidated financial statements as of December 31, 2007 and 2008 and for each of the years in the three-year period ended December 31, 2008, which have been audited by an independent registered public accounting firm, and their report thereon, is included elsewhere in this annual report on Form 20-F. You should read the selected consolidated financial data in conjunction with those financial statements and Item 5. Operating and Financial Review and Prospects included elsewhere in this annual report on Form 20-F. Our consolidated financial statements are prepared and presented in accordance with U.S. Generally Accepted Accounting Principles, or U.S. GAAP. Our historical results do not necessarily indicate our results expected for any future period.

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	Year Ended December 31,					
	2004 RMB	2005 RMB	2006 RMB	2007 RMB	2008 RMB	2008 $
	(in thousands, except share, per share and per ADS data)					
Selected Consolidated Statement of Income Data						
Total revenues[1]	564,198	737,014	950,606	1,368,748	1,741,143	255,206
Gross profit	410,403	565,940	760,046	1,127,667	1,420,261	208,173
Research and development expenses	(19,907)	(16,288)	(34,289)	(68,295)	(86,089)	(12,618)
Sales, marketing and distribution expenses	(230,865)	(312,426)	(442,757)	(634,449)	(782,960)	(114,762)
General and administrative expenses	(77,593)	(87,139)	(98,249)	(161,061)	(194,233)	(28,469)
Income from operations	82,038	150,087	184,751	263,862	356,979	52,324
Foreign currency exchange gains, net				24,670	39,879	5,845
Other income[1]				20,526	1,104	162
Net income[2][3]	46,245	102,745	172,258	301,261	350,151	51,323
Earnings per share basic	0.67	1.49	1.86	2.56	2.80	0.41
Earnings per share diluted	0.67	1.49	1.86	2.48	2.80	0.41
Earnings per ADS basic	1.34	2.98	3.72	5.13	5.61	0.82
Earnings per ADS diluted	1.34	2.98	3.72	4.95	5.60	0.82
Basic weighted average number of shares	69,000,000	69,000,000	92,695,890	117,534,566	124,921,934	124,921,934
Diluted weighted average number of shares	69,000,000	69,000,000	92,695,890	121,667,507	125,005,803	125,005,803

(1) Total revenues include product revenues and other revenue.

(2) In 2007 and 2008, other income

represented the incentive payment received from our depositary in connection with the establishment of the ADR program following our initial public offering. The incentive payment received in 2007 had the effect of increasing our 2007 net income by RMB20.5 million, or RMB0.17 per share on a basic basis and a diluted basis, or RMB0.35 per ADS on a basic basis and RMB0.34 on a diluted basis. The incentive payment received in 2008 had the effect of increasing our 2008 net income by RMB1.1 million ($0.2 million), or RMB0.01 ($0.001) per share on a basic basis and a diluted basis, or RMB0.02 ($0.003) per ADS on a basic basis and a diluted basis.

(3) In 2006, two of our operating subsidiaries were eligible for 100% tax exemptions under a tax holiday of a two-year 100% exemption followed by a

three-year 50% exemption commencing from the first profit-making year after offsetting accumulated tax losses, or 2+3 tax holiday. In 2007, four of our operating subsidiaries were eligible for 100% tax exemptions under 2+3 tax holiday, three of which expired at the end of 2007. In 2008, one and three of our operating subsidiaries were eligible for 100% and 50% tax exemptions from income tax, respectively; and two of our operating subsidiaries were qualified as advanced and new technology enterprises and eligible for a preferential income tax rate. The effect of the income tax exemptions and the preferential tax rate for advanced and new technology enterprises increased our net income for 2006, 2007 and 2008 by RMB38.8 million, RMB62.9 million and

RMB57.7 million ($8.5 million), respectively, or RMB0.42, RMB0.54 and RMB0.46 ($0.07) on the per share basis, respectively. Prior to 2006, there were no such tax exemptions and preferential tax arrangements in place.

	Year Ended December 31,				
	2004	**2005**	**2006**	**2007**	**2008**
			(in percentages)		
Other Consolidated Financial Data					
Gross margin	72.7	76.8	80.0	82.4	81.6
Operating margin	14.5	20.4	19.5	19.3	20.5
Net margin	8.2	13.9	18.2	22.0	20.1

	As of December 31,					
	2004 RMB	**2005 RMB**	**2006 RMB**	**2007 RMB**	**2008 RMB**	**2008 $**
			(in thousands)			
Selected Consolidated Balance Sheet Data						
Cash and cash equivalents	102,672	90,060	106,027	497,352	812,814	119,137
Held-to-maturity investment securities				470,000		
Accounts and bills receivables, net	99,987	130,871	162,781	488,374	748,997	109,783
Inventories	27,878	40,293	39,483	65,241	95,948	14,063
Amounts due from related parties	91,396	85,575	434	7,503	24,365	3,571
Total current assets	322,446	391,461	411,429	1,557,153	1,707,759	250,312
Property, plant and equipment, net	119,558	125,365	267,054	374,058	463,059	67,872
Intangible assets, net	18,020	15,731	163,148	251,221	275,244	40,344

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	As of December 31,					
	2004 RMB	2005 RMB	2006 RMB	2007 RMB	2008 RMB	2008 $
	(in thousands)					
Goodwill	13,814	13,814	100,634	161,496	178,211	26,121
Total assets	581,041	621,227	1,034,547	2,472,208	2,778,222	407,214
Short-term bank loans and borrowings and current installments of long-term debt	293,000	171,000	333,000	29,000	6,000	879
Amounts due to related parties	12,908	78,153	1,352			
Total current liabilities	456,747	421,185	568,173	342,637	335,013	49,103
Long-term debt, excluding current installments				52,000	62,000	9,088
Total shareholders equity	119,990	192,537	442,740	1,983,816	2,253,025	330,235

Exchange Rate Information

This annual report on Form 20-F contains translations of certain RMB amounts into U.S. dollar amounts at specified rates. Unless otherwise stated, the translations of RMB into U.S. dollars have been made at the noon buying rate in The City of New York for cable transfers of RMB as certified for customs purposes by the Federal Reserve Bank of New York, or the noon buying rate, on Wednesday, December 31, 2008, which was RMB6.8225 to $1.00. We make no representation that the RMB or U.S. dollar amounts referred to in this annual report on Form 20-F could have been, or could be, converted into U.S. dollars or RMB, as the case may be, at any particular rate or at all. See Item 3. Key Information. D. Risk Factors Risks Related to Doing Business in China Fluctuations in the value of the Renminbi may have a material adverse effect on your investment for discussions of the effects of fluctuating exchange rates and currency control on the value of our ADSs. On June 12, 2009, the exchange rate, as set forth in the H.10 statistical release of the Federal Reserve Board, was RMB6.8352 to $1.00.

The following table sets forth information concerning exchange rates between the RMB and the U.S. dollar for the periods indicated. These rates are provided solely for your convenience and are not necessarily the exchange rates that we used in this annual report or will use in the preparation of our periodic reports or any other information to be provided to you. For all periods prior to January 1, 2009, the exchange rate refers to the noon buying rate as reported by the Federal Reserve Bank of New York. For periods beginning on or after January 1, 2009, the exchange rate refers to the exchange rate as set forth in the H.10 statistical release of the Federal Reserve Board.

	RMB per U.S. Dollar Exchange Rate			
	Period End	Average[1]	Low	High
	(RMB per $1.00)			
2004	8.2765	8.2768	8.2774	8.2764
2005	8.0702	8.1826	8.2765	8.0702
2006	7.8041	7.9579	8.0702	7.8041
2007	7.2946	7.5806	7.8127	7.2946
2008	6.8225	6.9193	7.2946	6.7800
2008				

December 2009	6.8225	6.8539	6.8842	6.8225
January	6.8392	6.8360	6.8403	6.8225
February	6.8395	6.8363	6.8470	6.8241
March	6.8329	6.8360	6.8438	6.8240
April	6.8180	6.8304	6.8361	6.8180
May	6.8278	6.8235	6.8326	6.8176
June (through June 12)	6.8352	6.8328	6.8371	6.8264

(1) Annual averages are calculated from month-end rates. Monthly averages are calculated using the average of the daily rates during the relevant period.

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B. Capitalization and Indebtedness

Not Applicable.

C. Reasons for the Offer and Use of Proceeds

Not Applicable.

D. Risk Factors

Risks Related to Our Company

Our products and product candidates may not achieve or maintain widespread market acceptance.

Success of our products is highly dependent on the needs and preferences of healthcare practitioners and patients and market acceptance, and we may not achieve or maintain widespread market acceptance of our products or product candidates among healthcare practitioners and patients. We believe that market acceptance of our products will depend on many factors, including:

- the perceived advantages of our products over competing products and the availability and success of competing products;
- the effectiveness of our sales and marketing efforts;
- the safety and efficacy of our products and the prevalence and severity of adverse side effects, if any;
- our product pricing and cost effectiveness;
- publicity concerning our products, product candidates or competing products;
- whether or not patients routinely use our products, refill prescriptions and purchase additional products;
- our ability to respond to changes in healthcare practitioner and patient preferences; and
- the continued inclusion of our products in the Medical Insurance Catalogs.

If our products fail to achieve or maintain market acceptance, or if new products are introduced by others that are more favorably received than our products, are more cost effective or otherwise render our products obsolete, we may experience a decline in the demand for our products. If we are unable to market and sell our products successfully, our business, financial condition, results of operation and future growth would be adversely affected.

Our trademarks, patents and other non-patented intellectual property are valuable assets and if we are unable to protect them from infringement, our business prospects may be harmed.

As our own brand of generic products constitutes a large portion of our sales, we consider our trademarks to be valuable assets. Under PRC law, we have the exclusive right to use a trademark for products and services for which such trademark has been registered with the PRC Trademark Office of State Administration for Industry and Commerce. However, our efforts to defend our trademarks may be unsuccessful against competitors or other violating entities and we may not have adequate remedies for any breach. Our commercial success will also depend in part on our obtaining and maintaining patent and trade secret protection of our technologies, product candidates and products as well as successfully defending our patents against third-party challenges. We will only be able to protect our technologies, product candidates and products from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. In the event that our issued patents and our applications do

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not adequately describe, enable or otherwise provide coverage of our technologies, product candidates and products, we would not be able to exclude others from developing or commercializing these technologies, product candidates and products. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The patent situation outside of China may be more complex. Changes in either the patent laws or in interpretations of patent laws in China or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the scope of claims that may be allowed or enforced in our patents or in third-party patents. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our technologies without infringing our intellectual property rights;
- one or more of our pending patent applications may not result in issued patents;
- our issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- we may not develop additional proprietary technologies or product candidates that are patentable; and
- the patents of others may prevent us from developing or commercializing our product candidates.

We also rely on trade secrets to protect our technology, especially where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, our research partners employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our information to competitors or use our trade secrets without our authorization. In addition, confidentiality agreements, if any, executed by the foregoing persons may not be enforceable or provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, our enforcement efforts would be expensive and time-consuming, and the outcome would be unpredictable. In addition, if our competitors independently develop information that is equivalent to our trade secrets, it will be more difficult for us to enforce our rights and our business could be harmed.

If we are not able to obtain and defend our patents or trade secrets, we will not be able to exclude competitors from developing or marketing competing products using the relevant technologies or processes, thereby adversely affecting our competitiveness.

The existence of a patent may not necessarily protect us from competition as our patent may be challenged, invalidated or held unenforceable. We may also be found to infringe the patents of others.

The existence of a patent may not necessarily protect us from competition, as any patent issued may be challenged, invalidated, or held unenforceable. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents or produce products in countries that do not recognize our patents. The occurrence of any of these events could hurt our competitive position and decrease our revenues from product sales and/or licensing.

In addition, even if we own patents, this does not provide assurance that the manufacture, sale or use of our patented products does not infringe the patent rights of another. Because patent applications can take many years to

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approve and issue, there may be pending applications, known or unknown to us, that may later result in issued patents that our technologies, product candidates or products may infringe. Specifically, under the PRC Patent Law, the term of patent protection starts from the date the patent was filed, instead of the date it was issued as is the case in many jurisdictions. Therefore our priority in any PRC patents may be defeated by third-party patents issued on a later date if the applications for such patents were filed prior to our own, and the technologies underlying such patents are the same or substantially similar to ours. In such case, a third party with an earlier application may force us to pay to license its patented technology, sue us for patent infringement and/or challenge the validity of our patents. If a third party sues us for infringement, the suit will divert substantial management time and resources, regardless of whether we are ultimately successful. Further, we may be liable for monetary damages and/or forced to redesign, if possible, our technology to avoid the infringement.

Litigation to protect our intellectual property rights or defend against third-party allegations of infringement may be costly.

We may encounter future litigation by third parties based on claims that our products or activities infringe the intellectual property rights of others or that we have misappropriated the trade secrets of others. We may also initiate lawsuits to defend the ownership or inventorship of our inventions. It is difficult, if not impossible, to predict how such disputes would be resolved. The defense and prosecution of intellectual property rights are costly and divert technical and management personnel from their normal responsibilities. We may not prevail in any of such litigation or proceedings. An adverse determination of any litigation or proceedings against us, resulting in a finding of non-infringement by others or invalidity of our patents, may result in the sale by competitors of generic substitutes of our products. In addition, a determination that we have infringed on the intellectual property rights of another may require us to do one or more of the following:

- pay monetary damages to settle the results of such adverse determination, which could adversely affect our business, financial condition and results of operations;
- cease selling, incorporating or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue or costs, or both;
- obtain a license from the holder of the infringed intellectual property right, which might be costly or might not be available on reasonable terms, or at all; or
- redesign our products to make them non-infringing, which would be costly and time-consuming and may require additional clinical trials, or may not be possible at all.

While we currently know of no actual or threatened claim of infringement that would be material to us, there can be no assurance that such a claim will not be asserted. If such a claim is asserted, there can be no assurance that the resolution of the claim would permit us to continue producing the product in question on commercially reasonable terms. In addition, there is a risk that some of our confidential information could be compromised by disclosure during intellectual property litigation. Furthermore, there could be public announcements throughout the course of intellectual property litigation or proceedings as to the results of hearings, motions or other interim proceedings or developments in the litigation. If securities analysts or investors perceive these results to be negative, there could be a substantial negative effect on the trading price of our ADSs.

Most of our products are branded generics that can be manufactured and sold by other pharmaceutical manufacturers in China once the relevant protection or monitoring periods, if any, elapse.

Most of our products are branded generic pharmaceuticals and are not protected by patents. As a result, other pharmaceutical companies may sell equivalent products at a lower cost, and this might result in a commensurate loss in sales of our branded generic products. Certain of our generic products are subject to a protection or monitoring period. During such period, the PRC State Food and Drug Administration, or the SFDA, will not accept applications for new medicine certificates for the same product by other pharmaceutical companies or approve the production or import of the same product by other pharmaceutical companies. Once such protection or monitoring periods expire, other manufacturers may obtain relevant production approvals and will be entitled to

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sell generic pharmaceutical products with similar formulae or production methods in China. The maximum monitoring period currently granted by the SFDA is five years. The maximum protection period granted by the SFDA was eight years prior to April 1999, but was later increased to 12 years. As of March 31, 2009, our product Zaichang was under a monitoring period which is to expire on March 13, 2013 and our product Anxin was under a monitoring period which is to expire on May 3, 2012. If other pharmaceutical companies sell pharmaceutical products that are similar to our unprotected products or our protected products for which the relevant monitoring period has expired, we may face additional competition and our business and profitability may be adversely affected.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Certain of our employees and consultants were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, or at universities or other research institutions. Although no claims against us are currently pending, we may be subject to claims that these employees, consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could delay or prevent us from commercializing one or more of our product candidates.

Our future research and development projects may not be successful.

The successful development of pharmaceutical products can be affected by many factors. Products that appear to be promising at their early phases of research and development may fail to be commercialized for various reasons, including the failure to obtain the necessary regulatory approvals. In addition, the research and development cycle for new products for which we may obtain an approval certificate is long. The process of conducting basic research and various stages of tests and trials of a new product before obtaining an approval certificate and commercializing the product may require ten years or longer. Many of our product candidates are in the early stages of pre-clinical studies or clinical trials and we must conduct significant additional clinical trials before we can seek the necessary regulatory approvals to begin commercial production and sales of these products. For certain pharmaceuticals, such as Endu, we are required to conduct Phase IV clinical trials even after such product has obtained the necessary regulatory approvals to begin commercial production and sale, and if we fail to complete such Phase IV clinical trials within a specified period, we may be unable to renew the registration for such products. For Endu, such Phase IV clinical trials must be completed and the relevant report submitted prior to September 2010. There is no assurance that our future research and development projects will be successful or completed within the anticipated time frame or budget or that we will receive the necessary approvals from relevant authorities for the production of these newly developed products, or that these newly developed products will achieve commercial success. Even if such products can be successfully commercialized, they may not achieve the level of market acceptance that we expect.

In addition, the pharmaceutical industry is characterized by rapid changes in technology, constant enhancement of industrial know-how and frequent emergence of new products. Future technological improvements and continual product developments in the pharmaceutical market may render our existing products obsolete or affect their viability and competitiveness. Therefore, our future success will largely depend on our research and development capability, including our ability to improve our existing products, diversify our product range and develop new and competitively priced products that can meet the requirements of the changing market. Should we fail to respond to these frequent technological advances by improving our existing products or developing new products in a timely manner or these products do not achieve a desirable level of market acceptance, our business and profitability will be materially and adversely affected.

We rely on certain domestic and overseas research institutions and universities for the research and development of new products and any failure of our research partners to meet our timing and quality standards or our failure to continue such collaborative arrangement or enter into such new arrangements could adversely affect our ability to develop new pharmaceuticals and our overall business prospects.

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Our business strategy includes collaborating with third parties for research and development of new products. We rely on long-term cooperative relationships with a number of domestic and overseas research institutions and universities. These research institutions and universities have collaborated with us in a number of research projects and certain of our products that have obtained approval certificates were developed by us together with our research partners. At present, several research institutions and universities are working with us on various research and development projects. Any failure of our research partners to meet the required quality standards and timetables set in their research agreements with us, or our inability to enter into additional research agreements with these research partners on terms acceptable to us in the future, may have an adverse effect on our ability to develop new products and on our business prospects. In addition, the growth of our business and development of new products may require that we seek additional collaborative partners. We cannot assure you that we will be able to enter into agreements with collaborative partners on terms acceptable to us. Our inability to enter into such agreements or our failure to maintain such arrangements could limit the number of new products that we could develop and ultimately decrease our sources of future revenue.

We may not be able to obtain regulatory approval for any of the products resulting from our development efforts and failure to obtain these approvals could materially harm our business.

All new medicines must be approved by the SFDA before they can be marketed and sold in China. The SFDA requires successful completion of clinical trials and demonstrated manufacturing capability before it grants approval. Clinical trials are expensive and their results are uncertain. It often takes a number of years before a medicine can be ultimately approved by the SFDA. In addition, the SFDA and other regulatory authorities may apply new standards for safety, manufacturing, packaging, and distribution of future product candidates. Complying with such standards may be time-consuming and expensive and could result in delays in obtaining SFDA approval for our future product candidates, or possibly preclude us from obtaining SFDA approval altogether. Furthermore, our future products may not be effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use. The SFDA and other regulatory authorities may not approve the products that we develop and even if we do obtain regulatory approvals, such regulatory approvals may be subject to limitations on the indicated uses for which we may market a product, which may limit the size of the market for such product.

Our marketing activities are critical to the success of our products, and if we fail to grow our marketing capabilities or maintain adequate spending on marketing activities, the market share of our products and our brand name and product reputation would be materially adversely affected.

Most of our products are branded generic pharmaceuticals and the success and lifespan of our products are dependent on our efforts in the marketing of our products. Our marketing professionals regularly visit hospitals, clinics and pharmacies to explain the therapeutic value of our pharmaceuticals and to keep healthcare professionals up to date as to any developments relating to our pharmaceuticals. We organize in-person product presentations, conferences and seminars for physicians and other healthcare professionals and participate in trade shows to generate market awareness of our existing and new prescription pharmaceuticals. We are also engaged in advertising and educational campaigns through various media channels to educate the public as to our pharmaceuticals. These various marketing activities are critical to the success of our products. However, we cannot assure you that our current and planned spending on marketing activities will be adequate to support our future growth. Any factors adversely affecting our ability to grow our marketing capabilities or our ability to maintain adequate spending on marketing activities will have an adverse effect on the market share of our products and the brand name and reputation of our products, which may result in decreased demand for our products and negatively affect our business and results of operations.

We may not be successful in competing with other manufacturers of pharmaceuticals in the tender processes for the purchase of medicines by state-owned and state-controlled hospitals.

A substantial portion of the products we sell to our distributor customers are then sold to hospitals owned and controlled by counties or higher level government authorities in China. These hospitals must implement collective tender processes for the purchase of medicines listed in the Medical Insurance Catalogs and medicines that are consumed in large volumes and commonly prescribed for clinical uses. During a collective tender process, the

hospitals will establish a committee consisting of recognized pharmaceutical experts. The committee will assess

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the bids submitted by the pharmaceutical manufacturers, taking into consideration, among other things, the quality and price of the medicine and the service and reputation of the manufacturers. For the same type of pharmaceutical, the committee usually selects from among two to three different brands. Only pharmaceuticals that have won in the collective tender processes may be purchased by these hospitals. The collective tender process for pharmaceuticals with the same chemical composition must be conducted at least annually, and pharmaceuticals that have won in the collective tender processes previously must participate and win in the collective tender processes in the following period before new purchase orders can be issued. If we are unable to win purchase contracts through the collective tender processes in which we decide to participate, we will lose market share to our competitors, and our revenue and profitability will be adversely affected.

We may not be able to successfully identify and acquire new products or businesses.

In addition to our own research and development efforts, our growth strategy also relies on our acquisitions of new product candidates, products or businesses from third parties. Any future growth through acquisitions will be dependent upon the continued availability of suitable acquisition candidates at favorable prices and upon advantageous terms and conditions. Even if such opportunities are present, we may not be able to successfully identify such acquisition target. Moreover, other companies, many of which may have substantially greater financial, marketing and sales resources, are competing with us for the right to acquire such product candidates, products or businesses.

If an acquisition candidate is identified, the third parties with whom we seek to cooperate may not select us as a potential partner or we may not be able to enter into arrangements on commercially reasonable terms or at all. Furthermore, the negotiation and completion of potential acquisitions could cause significant diversion of management s time and resources and potential disruption of our ongoing business. Future acquisitions may also expose us to other potential risks which may adversely affect our business, financial condition and results of operations, including risks associated with:

- failure to obtain regulatory approval for any newly acquired product candidates;
- the integration of the acquired businesses, operations, services and personnel with our existing business and operations;
- the infringement of third parties intellectual property rights or intellectual property right challenges as to the acquired pharmaceuticals;
- unforeseen or hidden liabilities;
- the diversion of resources from our existing businesses and technologies;
- our inability to generate sufficient revenue to recover costs and expenses of the acquisitions; and
- potential loss of, or harm to, relationships with employees or customers, any of which could significantly disrupt our ability to manage our business and materially and adversely affect our business, financial condition and results of operations.

We depend on distributors for all of our revenues and failure to maintain relationships with our distributors or to otherwise expand our distribution network would materially and adversely affect our business.

We sell our products exclusively to pharmaceutical distributors in China and depend on distributors for all of our revenues. We have business relationships directly or indirectly with approximately 1,700 pharmaceutical distributors in China. In 2006, 2007 and 2008, no single distributor contributed, on an individual basis, 10.0% or more of our total revenues, and sales to our five largest distributors accounted in aggregate for approximately 12.7%, 13.8% and 11.6% respectively, of our product revenues. In line with industry practices in China, we typically enter into written distribution agreements with our distributors for one-year terms that are generally renewed annually. As our existing distribution agreements expire, we may be unable to renew with our desired distributors on favorable

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terms or at all. In addition, some of our distributors may sell products that compete with our products. We compete for desired distributors with other pharmaceutical manufacturers, many of which may have higher visibility, greater name recognition and financial resources, and broader product selection than we do. Consequently, maintaining relationships with existing distributors and replacing distributors may be difficult and time-consuming. Any disruption of our distribution network, including our failure to renew our existing distribution agreements with our desired distributors, could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, financial condition and results of operations.

We may not be able to effectively manage our employees, distribution network and third-party marketing firms, and our reputation, business, prospects and brand may be materially and adversely affected by actions taken by our distributors.

We have limited ability to manage the activities of our distributors and third-party marketing firms that we contract to promote our products and brand name, both of which are independent from us. Our distributors and third-party marketing firms could take one or more of the following actions, any of which could have a material adverse effect on our business, prospects and brand:

- sell our products outside their designated territory, possibly in violation of the exclusive distribution rights of other distributors;
- fail to adequately promote our products; or
- violate the anti-corruption laws of China, the United States or other countries.

In addition, although our company policies prohibit our employees from making improper payments to hospitals or otherwise engaging in improper activities to influence the procurement decisions of hospitals, we may not be able to effectively manage our employees, as the compensation of our sales and marketing personnel is partially linked to their sales performance. As a result, we cannot assure you that our employees will not violate the anti-corruption laws of China, the United States or other countries. Such violations could have a material adverse effect on our reputation, business, prospects and brand.

Failure to adequately manage our employees, distribution network or third-party marketing firms, or their non-compliance with employment, distribution or marketing agreements could harm our corporate image among end users of our products and disrupt our sales, resulting in a failure to meet our sales goals. Furthermore, we could be liable for actions taken by our employees, distributors or third-party marketing firms, including any violations of applicable law in connection with the marketing or sale of our products, including China s anti-corruption laws and the Foreign Corrupt Practices Act of the United States, or the FCPA. In particular, if our employees, distributors or third-party marketing firms make any payments that are forbidden under the FCPA, we could be subject to civil and criminal penalties imposed by the U.S. government.

Over the past few years, the PRC government has increased its anti-corruption measures. In the pharmaceutical industry, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from pharmaceutical manufacturers and distributors in connection with the prescription of certain pharmaceuticals. Our employees, affiliates, distributors or third-party marketing firms may violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products. If our employees, affiliates, distributors or third-party marketing firms violate these laws, we could be required to pay damages or fines, which could materially and adversely affect our financial condition and results of operations. In addition, PRC laws regarding what types of payments to promote or sell our products are impermissible are not always clear. As a result, we, our employees, affiliates, our distributors or third-party marketing firms could make certain payments in connection with the promotion or sale of our products or other activities involving our products which at the time are considered by us or them to be legal but are later deemed impermissible by the PRC government. Furthermore, our brand and reputation, our sales activities or the price of our ADSs could be adversely affected if we become the target of any negative publicity as a result of actions taken by our employees, affiliates, distributors or third-party marketing firms. In

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addition, government-sponsored anti-corruption campaigns from time to time could have a chilling effect on our marketing efforts to new hospital customers.

There is no assurance that our existing products will continue to be included or new products developed by us will be included in the Medical Insurance Catalogs.

Eligible participants in the national basic medical insurance program in China, which consists of mostly urban residents, are entitled to reimbursement from the social medical insurance fund for up to the entire cost of medicines that are included in the Medical Insurance Catalogs. See Item 4. Information of the Company B. Business Overview Regulation Reimbursement Under the National Medical Insurance Program. As of March 31, 2009, 24 of our 45 principal products that were manufactured and sold were included in the national Medical Insurance Catalog and 15 were included in the provincial Medical Insurance Catalogs of various provinces, municipalities and autonomous regions. The inclusion of a medicine in the Medical Insurance Catalogs can substantially improve the sales of the medicine. The Ministry of Human Sources and Social Security in China, or the Ministry of Human Resources, together with other government authorities from time to time, selects medicines to be included in the Medical Insurance Catalogs based on factors including treatment requirements, frequency of use, effectiveness and price. The Ministry of Human Resources also occasionally removes medicines from such catalogs. There can be no assurance that our existing products will continue to be included in the Medical Insurance Catalogs. The removal or exclusion of our products from the Medical Insurance Catalogs may adversely affect our sales. In addition, there is significant uncertainty related to the coverage and reimbursement of newly approved pharmaceutical products. The commercial success of our potential products is substantially dependent on whether reimbursement is available for the ordering of our potential products by hospitals for use by their patients. Our failure to obtain inclusion of our potential products to the Medical Insurance Catalogs may adversely affect the future sales of those products.

We have limited insurance coverage and may incur losses resulting from product liability claims or business interruptions.

The nature of our business exposes us to the risk of product liability claims that is inherent in the research and development, manufacturing and marketing of pharmaceutical products. Using product candidates in clinical trials also exposes us to product liability claims. These risks are greater for our products that receive regulatory approval for commercial sale. Even if a product were approved for commercial use by an appropriate governmental agency, there can be no assurance that users will not claim effects other than those intended resulted from the use of our products. While to date no material claim for personal injury resulting from allegedly defective products has been brought against us, a substantial claim or a substantial number of claims, if successful, could have a material adverse impact on our business, financial condition and results of operations. Such lawsuits may divert the attention of our management from our business strategies and may be costly to defend. In addition, we do not maintain product liability insurance or insurance covering potential liability relating to the release of hazardous materials. In the event of allegations that any of our products are harmful, we may experience reduced consumer demand for our products or our products may be recalled from the market. We may also be forced to defend lawsuits and, if unsuccessful, to pay a substantial amount in damages. In addition, business interruption insurance available in China offers limited coverage compared to that offered in many other countries. We do not have any business interruption insurance. Any business disruption or natural disaster could result in substantial costs and diversion of resources.

Our revenue depends and will likely continue to depend on a limited number of product lines.

We currently have four products that individually contribute over RMB100.0 million ($14.7 million) to our revenues in 2008, which were Bicun, Zailin, Endu and Yingtaiqing. Sales of these products accounted in aggregate for 71.8% of our product revenues in 2008. We expect sales of these limited product lines to comprise a substantial portion of our revenues in the future. Accordingly, any factors adversely affecting the sales of any of these products will have a material adverse effect on our business, financial condition and results of operations.

Our limited operating history may not serve as an adequate basis to judge our future prospects and results of operations.

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We commenced operations in March 1995 and operated our business mainly as a distributor of pharmaceutical products. Since then, we have gradually built up our research, development and manufacturing capabilities and have become an integrated pharmaceutical company that develops, manufactures and sells pharmaceutical products. Therefore we have a limited operating history under our current business model upon which you can evaluate the viability and sustainability of our business. Accordingly, you should consider our future prospects in light of the risks and uncertainties experienced by other China-based early stage companies. Some of these risks and uncertainties relate to our ability to:

- retain and acquire customers;
- diversify our revenue sources by successfully developing and selling new products;
- effectively manage our business as it expands;
- respond to changes in our regulatory environment;
- manage risks associated with intellectual property rights;
- maintain effective control of our costs and expenses;
- raise sufficient capital to sustain and expand our business; and
- attract, retain and motivate qualified personnel.

If we are unsuccessful in addressing any of these risks and uncertainties, our business, financial condition, results of operations and future growth would be adversely affected.

We may not be able to manage our expansion of operations effectively.

We commenced business operations in March 1995, changed our business model in 2001, and have grown rapidly. We anticipate significant continued expansion of our business to address growth in demand for our products, as well as to capture new market opportunities. To manage the potential growth of our operations, we will be required to improve our operational and financial systems, procedures and controls, increase manufacturing capacity and output, and expand, train and manage our growing employee base. Furthermore, we need to maintain and expand our relationships with our customers, suppliers and other third parties. We cannot assure you that our current and planned operations, personnel, systems, internal procedures and controls will be adequate to support our future growth. In addition, the success of our growth strategy depends on a number of internal and external factors, such as the expected growth of the pharmaceutical market in China and the competition from other pharmaceutical companies. If we are unable to manage our growth effectively, we may not be able to take advantage of market opportunities, execute our business strategies or respond to competitive pressures.

We have no control over Hong Kong Medgenn or the development and sale of Endu outside of the PRC. Our brand and reputation may be adversely affected if the development and sale of Endu outside of the PRC violate the intellectual property rights of any third parties.

Medgenn (Hong Kong) Co., Ltd., or Hong Kong Medgenn, an affiliate company in which we owned indirectly an effective 40.0% equity interest as of March 31, 2009, has the ability to engage in the development and sale of Endu in any jurisdiction outside of the PRC, including the United States, until February 10, 2015. The other 60.0% of Hong Kong Medgenn was owned by Bestspeed Investments Limited, or Bestspeed, a British Virgin Islands company. Hong Kong Medgenn is controlled by its board of directors, which has five members, including Dr. Yongzhang Luo, Mr. Willi Chu and Mr. Linghai Zhu, all of whom were appointed by Bestspeed, and Mr. Jinsheng Ren and Mr. Xiaojin Yin, both of whom were appointed by Shandong Simcere Medgenn Bio-Pharmaceutical Co., Ltd., or Shandong Simcere, formerly known as Yantai Medgenn Co., Ltd., and are also our executive officers. Bestspeed was a shareholder of Hong Kong Medgenn prior to our acquisition of an 80.0% equity interest in Shandong Simcere in May 2006 and we are unable to ascertain the identities of the natural persons who

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control Bestspeed. We are not aware of whether Hong Kong Medgenn has commenced any operations to date, or whether it has obtained any regulatory approval outside of the PRC to sell Endu. Hong Kong Medgenn holds the rights to apply for patents and may grant its rights with respect to Endu in these jurisdictions to independent third parties. A cooperation agreement entered into on February 10, 2005 between Bestspeed and Shandong Simcere provides Bestspeed with daily operating control over Hong Kong Medgenn s business, including the development and sale of Endu in any jurisdiction outside of the PRC until February 10, 2015. If Hong Kong Medgenn violates the intellectual property rights of any third parties or otherwise suffers economic or other losses, our brand, reputation, business and results of operations could be adversely affected. In addition, the agreements with Hong Kong Medgenn will prohibit us from engaging in the development and sale of Endu outside of the PRC prior to February 10, 2015, which might hinder our ability to grow our business outside of the PRC.

Our business depends substantially on the continuing efforts of our executive officers, research personnel and other key personnel, and our business may be severely disrupted if we lose their services.

We depend on key members of our management team, research personnel and other key personnel. In particular, we depend on the services of Mr. Jinsheng Ren, our founder, the chairman of our board of directors and our chief executive officer, and Mr. Xiaojin Yin, our senior vice president of research and development. The loss of key employees could delay the advancement of our research and development activities. The implementation of our business strategy and our future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel. We face competition for personnel from other pharmaceutical companies, universities, public and private research institutions and other organizations. The process of hiring suitably qualified personnel is often lengthy. If our recruitment and retention efforts are unsuccessful in the future, it may be more difficult for us to execute our business strategy.

We do not maintain key employee insurance. If one or more of our executive officers, research personnel and other key personnel are unable or unwilling to continue in their present positions, we may not be able to replace them readily, if at all. Therefore, our business may be severely disrupted, and we may incur additional expenses to recruit and retain new officers. In addition, if any of our executive officers or key research personnel joins a competitor or forms a competing company, we may lose some of our customers. Each of our executive officers, key research personnel and marketing managers has entered into a confidentiality and non-competition agreement with us. However, if any disputes arise between our executive officers, key research personnel and marketing managers and us, we cannot assure you, in light of uncertainties associated with the PRC legal system, the extent to which any of these agreements could be enforced in China, where some of our executive officers reside and hold some of their assets. See

Risks Related to Doing Business in China Uncertainties with respect to the PRC legal system could have a material adverse effect on us.

Delays in production due to regulatory restrictions or other factors could have a material adverse impact on our business.

We manufacture substantially all of our products in our own manufacturing facilities. The manufacture of pharmaceutical products requires precise and reliable controls and regulatory authorities in China have imposed significant compliance obligations to regulate the manufacturing of pharmaceutical products. As a result, we may face delays in production due to regulatory restrictions or other factors. In addition, three of our generic pharmaceuticals, the Yingtaiqing-branded diclofenac sodium capsules, the Faneng-branded alfacalcidol soft capsules and the Yineng-branded generic lentinan injection, are all manufactured by independent third party manufacturers. Our contract manufacturers may not be able to manufacture our products without interruption, may not comply with their obligations under our various supply arrangements, and we may not have adequate remedies for any breach. Failure by our own manufacturing facility or any third party product supplier to comply with regulatory requirements could adversely affect our ability to provide products. All facilities and manufacturing techniques used for the manufacture of pharmaceutical products must be operated in conformity with Good Manufacturing Practices, or GMPs. In complying with GMP requirements, we and our product suppliers must continually spend time, money and effort in production, record-keeping and quality assurance and control to ensure that the product meets applicable specifications and other requirements for product safety, efficacy and quality. Manufacturing facilities are subject to periodic unannounced inspections by the SFDA and other regulatory authorities. In addition, adverse experiences with

the use of products must be reported to the SFDA and could result in the imposition of market restrictions through labeling changes or in product removal.

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Suppliers of certain active and inactive pharmaceutical ingredients and certain packaging materials used in our products are required to obtain SFDA approval before they may supply us with such materials. The development and regulatory approval of our products are dependent upon our ability to procure these ingredients, packaging materials and finished products from SFDA-approved sources. SFDA approval of a new supplier would be required if, for example, an existing supplier breached its obligations to us, active ingredients, packaging materials or finished products were no longer available from the initially approved supplier or if a supplier had its approval from the SFDA withdrawn. The qualification of a new product supplier could potentially delay the manufacture of the product involved. Furthermore, we may not be able to obtain active ingredients, packaging materials or finished products from a new supplier on terms that are at least as favorable to us as those agreed with the initially approved supplier or at reasonable prices.

A delay in supplying, or failure to supply, products by any product supplier could result in our inability to meet the demand for our products and adversely affect our revenues, financial condition, results of operations and cash flows.

Our operating results may fluctuate considerably on a quarterly basis. These fluctuations could have an adverse effect on the price of our shares and ADSs.

Our results of operations may fluctuate significantly on a quarterly basis as a result of a number of factors, many of which are beyond our control. Although many companies may encounter this problem, it is particularly relevant to us because of our relatively small size, our limited operating history, our reliance on limited number of products and the dynamics of the Chinese pharmaceutical industry in which we operate. Factors that could cause our results of operations to fluctuate include, among others:

- the seasonal fluctuations in demand for our products, especially our antibiotics, such as Zailin and Anqi;
- timing of research and development expenses;
- regulatory events;
- new product introductions by us or our competitors;
- variations in the demand for products we may introduce;
- litigation involving patents, licenses or other intellectual property; and
- product liability lawsuits.

Any of the foregoing factors could cause us to fail to meet the expectations of securities analysts or investors, which could cause the trading price of our shares and ADSs to decline.

Our future liquidity needs are uncertain and we may need to raise additional funds in the future.

We may, from time to time, need to raise funds as part of our business operations if our expenditures exceed our expectations. This could occur for a number of reasons, including:

- we determine to devote significant amount of financial resources to the research and development of projects that we believe to have significant commercialization potential;
- we determine to acquire or license rights to additional product candidates or new technologies;
- some or all of our product candidates fail in clinical trials or pre-clinical studies or prove to be not as commercially promising as we expect and we are forced to develop or acquire additional product candidates;

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- our product candidates require more extensive clinical or pre-clinical testing or clinical trials of these product candidates take longer to complete than we currently expect; or

- we determine or are required to conduct more high-throughput screening than expected against current or additional disease targets to develop additional product candidates.

Our ability to raise additional funds in the future is subject to a variety of uncertainties, including:

- our future financial condition, results of operations and cash flows;

- general market conditions for capital-raising activities by pharmaceutical companies; and

- economic, political and other conditions in China and elsewhere.

We cannot assure you that our revenues will be sufficient to meet our operational needs and capital requirements. If we need to obtain external financing, we cannot assure you that financing will be available in amounts or on terms acceptable to us, if at all. Our future liquidity needs and other business reasons could require us to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity or equity-linked securities could result in additional dilution to our shareholders. The incurrence of additional indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations.

A significant amount of intangible assets and goodwill are recorded on our balance sheet. Future impairment of our intangible assets or goodwill could have a material adverse impact on our financial condition and results of operations.

As of December 31, 2008, our net intangible assets amounted to RMB275.2 million ($40.3 million), representing 9.9% of our total assets, and goodwill amounted to RMB178.2 million ($26.1 million), representing 6.4% of our total assets. Besides goodwill, our intangible assets primarily consisted of developed technology and product trademarks that we acquired in connection with our acquisition of a 90.0% equity interest in Shandong Simcere, a 51.0% equity interest in Jilin Boda Pharmaceutical Co., Ltd., or Jilin Boda, an 85.71% equity interest in Nanjing Tung Chit Pharmaceutical Company Limited, or Nanjing Tung Chit, and a 70.0% equity interest in Wuhu Zhong Ren Pharmaceutical Co., Ltd., or Wuhu Simcere Zhong Ren, during 2006, 2007 and 2008. Developed technology represents the right to use, manufacture, market and sell the acquired products as well as their related invention patents in the PRC or the United States, as the case may be, while trademarks represent the right by the trademark registrant to use the registered trademark and to protect products from infringement. Our newly acquired principal products as of December 31, 2008 include Sinofuan, Endu, Yidasheng and Jiebaishu. Our developed technology and trademarks amounted to RMB249.0 million ($36.5 million), representing 9.0% of our total assets as of December 31, 2008. We estimated the fair value of the developed technology of the acquired products using their respective present values of projected cash flows based on assumptions with respect to the growth rate of our revenues from sales, the earnings before interest and tax margin derived from sales, the discount rate selected to measure the risks inherent in future cash flows and our assessment of the product life cycle. We also took into consideration the competitive trends that may affect these products sales, including consideration of any technical, legal, regulatory, and economic barriers to entry. See Item 5. Operating and Financial Review and Prospects A. Operating Results Critical Accounting Policies Long-Lived Assets and Goodwill. We determined the useful life of the developed technology of an acquired product by considering the remaining protection period of such product s patent in China and the expected competitive trend in the PRC market. While no impairment write-downs or change in useful life have been necessary to date, future events such as market acceptance of the acquire products, introduction of superior pharmaceuticals by our competitors, regulatory actions, safety concerns as to our pharmaceuticals, and challenges to and infringement of our intellectual property rights, could have a material impact on our key assumptions in determining the fair value of the developed technology of the acquired products. This in turn could result in write-downs of our intangible assets or goodwill, or a change in the useful lives of our intangible assets. Future write-downs of our intangible assets or goodwill, or change in useful lives of our intangible assets, could decrease our net income, which would have a

material adverse impact on our financial condition and results of operations.

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Our non-public shareholders have substantial influence over our company and their interests may not be aligned with the interests of our other shareholders.

As of the date of this annual report on Form 20-F, we had a number of shareholders other than public shareholders holding our ordinary shares in the form of ADSs, including New Good Management Limited, a company beneficially owned by 16 individuals, including certain of our senior management, and controlled by Mr. Jinsheng Ren, our founder, chief executive officer and chairman of our board of directors; Assure Ahead Investments Limited, an investment vehicle owned and controlled by a group of financial investors; and King View Development International Limited, an investment vehicle owned and controlled by Trustbridge Partners, a private equity fund. As of May 31, 2009, New Good Management Limited owned approximately 43.1% of our outstanding share capital, and Assure Ahead Investments Limited and King View Development International Limited owned 15.3% and 10.1% of our outstanding share capital, respectively. As such, they have substantial influence over our business, including decisions regarding mergers, consolidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions. This concentration of ownership may discourage, delay or prevent a change in control of our company, which could deprive our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and might reduce the price of our ADSs.

Our production activities involve the controlled use of potentially harmful biological materials as well as hazardous materials and chemicals.

Our production activities involve the controlled use of potentially harmful biological materials as well as hazardous materials and chemicals. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for damages that result, which could exceed our resources. We are subject to national, provincial and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We believe we are currently in compliance with these laws and regulations. However, any failure by us to control the use, storage, handling and disposal of these hazardous materials and chemicals could subject us to potentially significant monetary damages and fines or suspensions of our business operations. In addition, we do not currently carry any insurance for potential liabilities relating to the release of hazardous materials as such insurance is not currently available in China.

New labor laws in the PRC may adversely affect our results of operations.

On June 29, 2007, the PRC government promulgated a new labor law, namely, the Labor Contract Law of the PRC, or the New Labor Contract Law, which became effective on January 1, 2008. The Implementation Rules of the New Labor Contract Law was subsequently promulgated and became effective on September 18, 2008. The PRC government also promulgated the Law on Mediation and Arbitration of Labor Disputes on December 29, 2007 that came into effect on May 1, 2008. These newly enacted labor laws and regulations impose greater liabilities on employers and significantly impact the cost of an employer s decision to reduce its workforce. Further, they require certain terminations to be based upon seniority but not merit. In the event we decide to significantly change or decrease our workforce, the New Labor Contract Law could adversely affect our ability to enact such changes in a manner that is most advantageous to our business or in a timely and cost effective manner, thus materially and adversely affecting our financial condition and results of operations.

If we grant additional employee share options, restricted shares or other share-based compensation in the future, our net income could be adversely affected.

We adopted a share incentive plan on November 13, 2006. We issued 10,000,000, 1,045,000, 400,000 and 100,000 share options under our 2006 share incentive plan on November 15, 2006, March 29, 2007, May 5, 2008, and December 24, 2008, respectively. On July 31, 2008, our shareholders approved our 2008 share incentive plan under which we are authorized to issue up to 6,250,000 ordinary shares upon exercise of awards granted thereunder. As of May 31, 2009, no award was issued under our 2008 share incentive plan.

On April 15, 2009, our compensation committee approved a share option exchange program that offered our eligible employees and directors the right to exchange vested and unvested outstanding share options to purchase our ordinary shares under the 2006 Share Incentive Plan for restricted shares. The exchange ratio was

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determined based on the fair value of replacement restricted shares so that the fair value of the replacement restricted shares to be issued upon exchange would be approximately equivalent to the fair value of the share options surrendered by an individual. In addition, these replacement restricted shares are subject to substantially the same vesting schedule as the options that were validly tendered in the exchange offer. The exchange of the share option awards for restricted shares was accounted for as a modification for awards which involves a cancellation of the original award and an issuance of a new award. The replacement restricted shares were granted on May 7, 2009. We do not expect the effect of this award modification on share-based compensation expense over the remaining requisite service period to be significant.

We account for share-based compensation in accordance with Financial Accounting Standards Board Statement No. 123(R), Share-Based Payment, which requires a company to recognize, as an expense, the fair value of share options and other share-based compensation to employees based on the fair value of equity awards on the date of the grant, with the compensation expense recognized over the period in which the recipient is required to provide service in exchange for the equity award. If we grant additional options, restricted shares and other equity incentives in the future, we could incur significant compensation charges and our net income could be adversely affected.

Counterfeit pharmaceuticals in China could negatively impact our revenues, brand reputation, business and results of operations.

Our products are also subject to competition from counterfeit pharmaceuticals, which are pharmaceuticals manufactured without proper licenses or approvals and are fraudulently mislabeled with respect to their content and/or manufacturer. Counterfeiters may illegally manufacture and market pharmaceuticals under our brand name or that of our competitors. Counterfeit pharmaceuticals are generally sold at lower prices than the authentic products due to their low production costs, and in some cases are very similar in appearance to the authentic products. Counterfeit pharmaceuticals may or may not have the same chemical content as their authentic counterparts. If counterfeit pharmaceuticals illegally sold under our brand name results in adverse side effects to consumers, we may be associated with any negative publicity resulting from such incidents. In addition, consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. Although the PRC government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. Any such increase in the sales and production of counterfeit pharmaceuticals in China, or the technological capabilities of the counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Inappropriate use of our trade names by other entities could negatively affect our business.

Our trade name Simcere is also used by companies which are partially owned and controlled by certain shareholders of New Good Management Limited. If any such entity or any company that is unrelated to us uses the trade name Simcere in ways that negatively affect such trade names, our reputation could suffer harm, which in turn could have a material adverse effect on our financial condition and results of operations.

We may be classified as a passive foreign investment company, which could result in adverse United States federal income tax consequences to U.S. holders.

We believe that we were not a passive foreign investment company , or PFIC, for U.S. federal income tax purposes for our taxable year ending on December 31, 2008, and we do not expect to become one for our current taxable year or in the future, although there can be no assurance in this regard. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75.0% of its gross income is passive income or (2) at least 50.0% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The market value of our assets may be determined in large part by the market price of our ADSs and ordinary shares, which is likely to fluctuate. In addition, the composition of our income and assets will be affected by how, and how quickly, we spend the cash we receive. If we are treated as a PFIC for any taxable year during which U.S. holders hold ADSs or ordinary shares,

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certain adverse United States federal income tax consequences could apply to U.S. holders. See Taxation United States Federal Income Taxation Passive Foreign Investment Company.

If a poll is not demanded at our shareholder meetings, voting will be by show of hands and shares will not be proportionately represented. Shareholder resolutions may be passed without the presence of the majority of our shareholders in person or by proxy.

Voting at any of our shareholder meetings is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of the meeting or by any shareholder present in person or by proxy. If a poll is demanded, each shareholder present in person or by proxy will have one vote for each ordinary share registered in his name. If a poll is not demanded, voting will be by show of hands and each shareholder present in person or by proxy will have one vote regardless of the number of shares registered in his name. In the absence of a poll, shares will therefore not be proportionately represented. In addition, the quorum required for our shareholder meetings consists of shareholders who hold at least one-third of our ordinary shares being present at a meeting in person or by proxy. Therefore, subject to the requisite majorities, shareholder resolutions may be passed at our shareholder meetings without the presence of the majority of our shareholders in person or by proxy.

Risks Related to Our Industry

Changes in economic conditions and consumer confidence in China may influence consumer preferences and spending patterns, and accordingly, our results of operations.

Our business and revenue growth primarily depend on the size of the pharmaceutical products in China. As a result, our revenue and profitability may be negatively affected by changes in national, regional or local economic conditions and consumer confidence in China. In particular, as we focus our expansion of retail stores in metropolitan markets, where living standards and consumer purchasing power are higher than rural areas, we are especially susceptible to changes in economic conditions, consumer confidence and customer preferences of the urban Chinese population. External factors beyond our control that affect consumer confidence include unemployment rates, levels of personal disposable income, national, regional or local economic conditions and acts of war or terrorism. Changes in economic conditions and consumer confidence could adversely affect consumer preferences, purchasing power and spending patterns. For example, the recent global economic and financial market crisis has caused, among other things, lower customer spending across China. As a result, sales of our premium priced high-end anti-cancer medication Endu, which is currently excluded from national medical insurance catalogue, have declined and may continue to decline as patients decrease their purchases as a result of worries about economic conditions or reduced incomes. In addition, the timing and nature of any recovery in the credit and financial markets remains uncertain, and there can be no assurance that market conditions will improve in the near future or that our results will not continue to be materially and adversely affected. In addition, acts of war or terrorism may cause damage to our facilities, disrupt the supply of the products and services we offer in our stores or adversely impact consumer demand. Any of these factors could have a material adverse effect on our business, financial condition and results of operations.

We face intense competition that may prevent us from maintaining or increasing market share for our existing products and gaining market acceptance for our future products. Our competitors may develop or commercialize products before us or more successfully than us.

The pharmaceutical market in China is intensely competitive, rapidly evolving and highly fragmented. Our competitors may develop products that are superior to ours or may be more effective in marketing products that are competitive with ours. We face competition from other pharmaceutical companies, including multinational companies as well as manufacturers of traditional Chinese medicines with similar curative effects that can be used as substitutes for certain of our products.

Many of our existing and potential competitors may have greater financial, technical, manufacturing and other resources than we do. In addition, certain competitors which were established by multinational pharmaceutical companies, have more extensive research and development and technical capabilities than we do. Furthermore, China s industry reforms aimed to meet the World Trade Organization, or the WTO, requirements may foster increased competition from multinational pharmaceutical companies. Such competitors may also have greater brand

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name recognition, more established distribution networks, larger customer bases or more extensive knowledge of our target markets. Our competitors greater size in some cases provides them with a competitive advantage with respect to manufacturing costs because of their economies of scale and their ability to purchase raw materials at lower prices. As a result, they may be able to devote greater resources to the research, development, promotion and sale of their products or respond more quickly to evolving industry standards and changes in market conditions than we can. In addition, certain of our competitors may adopt low-margin sales strategies and compete against us based on lower prices. Our failure to adapt to changing market conditions and to compete successfully with existing or new competitors may materially and adversely affect our financial condition and results of operations.

In addition, to increase sales, certain manufacturers or distributors of pharmaceuticals may engage in questionable practices in order to influence procurement decisions of our customers. As a result, as competition intensifies in the pharmaceutical industry in China, we may lose sales, customers or contracts to competitors that engage in these practices.

The retail prices of certain of our products are subject to control, including periodic downward adjustment, by PRC government authorities.

Certain of our pharmaceutical products, primarily those included in the national and provincial Medical Insurance Catalogs, are subject to price controls in the form of fixed retail prices or retail price ceilings. See Item 4. Information of the Company B. Business Overview Regulation Price Controls. In addition, the maximum retail prices of products that are included in the Medical Insurance Catalogs are also subject to periodic downward adjustments as the PRC government authorities aim to make pharmaceuticals more affordable to the general public. However, PRC government authorities impose no control over the prices at which pharmaceutical manufacturers sell their products to their distributors. Since May 1998, the relevant PRC government authorities have ordered price reductions of various pharmaceuticals 24 times. The latest price reductions occurred in January, March, April and May of 2007 and affected a total of 466 different Chinese medicines and 614 different western pharmaceuticals. The retail price ceilings of our major products Anqi and Zailin, both of which are included in the national Medical Insurance Catalog, were adjusted downward in June 2004, and the retail price ceilings of our Faneng branded alfacalcidol soft capsules and Simcere Kechuanning branded herbal cough medicine were adjusted downward in January and March 2007, respectively. As of March 31, 2009, we have not adjusted our selling prices of Faneng and Simcere Kechuanning downward because their actual retail prices were below their retail price ceilings after the price reductions. We do not plan to make adjustments to our prices of Faneng and Simcere Kechuanning in the near future. However, in the long term, the prices at which pharmaceutical manufacturers in China sell their products to distributors, including the prices of our products, will be affected by the relevant fixed retail prices or retail price ceilings. Government price controls, especially downward price adjustments, may have a material adverse effect on our revenues and profitability.

Pharmaceutical companies in China require a number of permits and licenses in order to carry on their business.

All pharmaceutical manufacturing and distribution companies in China are required to obtain certain permits and licenses from various PRC governmental authorities, including, in the case of manufacturing companies, a pharmaceutical manufacturing permit and, in the case of distribution companies, a pharmaceutical distribution permit. See Item 4. Information of the Company B. Business Overview Regulation.

We have obtained permits and licenses and GMP certifications required for the manufacture of our pharmaceutical products. In addition, we have obtained permits, licenses and Good Supply Practice, or GSP, certifications for the distribution of our products. Each of these permits and licenses held by us is valid for five years and subject to periodic renewal and/or reassessment by the relevant PRC government authorities and the standards of compliance required in relation thereto may from time to time be subject to changes. For example, the current pharmaceutical manufacturing permit for each of Simcere Pharmaceutical Co., Ltd., or Hainan Simcere, Nanjing Simcere Dongyuan Pharmaceutical Co., Ltd., or Nanjing Simcere, Shandong Simcere, Jilin Boda, Nanjing Tung Chit and Wuhu Simcere Zhong Ren, will all expire on December 31, 2010. In addition, Jilin Boda is currently expanding its facilities which then require it to renew its existing manufacturing permit. The 20 GMP certificates for our six manufacturing facilities will expire between August 2009 and May 2014, and the two GSP certificates held by two of our distribution subsidiaries will expire in July 2013 and November 2013, respectively. See Item 4. Information of the Company B. Business Overview Regulation. We intend to apply for the renewal of such

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permits and licenses when required by applicable laws and regulations. Any failure by us to obtain such renewals may have a material adverse effect on the operation of our business, and prevent us from continuing to carry on our business. Furthermore, any changes in compliance standards, or any new laws or regulations may prohibit or render it more restrictive for us to conduct our business or may increase our compliance costs, which may adversely affect our operations or profitability.

Risks Related to Doing Business in China

Uncertainties with respect to the PRC legal system could have a material adverse effect on us.

The PRC legal system is a civil law system based on written statutes. Unlike in the common law system, prior court decisions may be cited for reference but have limited precedential value. Since 1979, PRC legislation and regulations have significantly enhanced the protections afforded to various forms of foreign investments in China. We conduct all of our business through our subsidiaries established in China. These subsidiaries are generally subject to laws and regulations applicable to foreign investment in China and, in particular, laws applicable to wholly foreign-owned enterprises. However, since these laws and regulations are relatively new and the PRC legal system continues to rapidly evolve, the interpretations of many laws, regulations and rules are not always uniform and enforcement of these laws, regulations and rules involve uncertainties, which may limit legal protections available to us. For example, we may have to resort to administrative and court proceedings to enforce the legal protection that we enjoy either by law or contract. However, since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into with our business partners, customers and suppliers. In addition, such uncertainties, including the inability to enforce our contracts, could materially and adversely affect our business and operations. Furthermore, intellectual property rights and confidentiality protections in China may not be as effective as in the United States or other countries. Accordingly, we cannot predict the effect of future developments in the PRC legal system, particularly with regard to the Chinese pharmaceutical industry, including the promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, or the preemption of local regulations by national laws. These uncertainties could limit the legal protections available to us and other foreign investors, including you. In addition, any litigation in China may be protracted and result in substantial costs and diversion of our resources and management attention.

Adverse changes in political and economic policies of the PRC government could have a material adverse effect on the overall economic growth of China, which could reduce the demand for our products and materially and adversely affect our competitive position.

All of our business operations are conducted in China and all of our sales are made in China. Accordingly, our business, financial condition, results of operations and prospects are affected significantly by economic, political and legal developments in China. The Chinese economy differs from the economies of most developed countries in many respects, including:

the degree of government involvement;

the level of development;

the growth rate;

the control of foreign exchange;

access to financing; and

the allocation of resources.

While the Chinese economy has grown significantly in the past, the growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures

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to encourage economic growth and guide the allocation of resources. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us.

The Chinese economy has been transitioning from a planned economy to a more market-oriented economy. Although in recent years the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets and the establishment of sound corporate governance in business enterprises, a substantial portion of the productive assets in China is still owned by the PRC government. The continued control of these assets and other aspects of the national economy by the PRC government could materially and adversely affect our business. The PRC government also exercises significant control over China s economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies. As a result, actions and policies of the PRC government could materially affect our liquidity and access to capital and our ability to operate our business.

We rely on dividends paid by our subsidiaries for our cash needs, and any limitation on the ability of our subsidiaries to make payments to us could have a material adverse effect on our ability to conduct our business.

We conduct all of our business through our subsidiaries established in China. We rely on dividends paid by these subsidiaries for our cash needs, including the funds necessary to pay dividends and other cash distributions to our shareholders, to service any debt we may incur and to pay our operating expenses. The payment of dividends by entities established in China is subject to limitations. Regulations in China currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in China. Each of our PRC subsidiaries including wholly foreign-owned enterprises, or WFOEs, and domestic companies is also required to set aside at least 10.0% of its after-tax profit based on PRC accounting standards each year to its general reserves or statutory capital reserve fund until the accumulative amount of such reserves reach 50.0% of its respective registered capital. As of December 31, 2008, our restricted reserves amounted to RMB133.9 million ($19.6 million), and our accumulated profits that were unrestricted and were available for distribution amounted to RMB686.4 million ($100.6 million). Our restricted reserves are not distributable as cash dividends. In addition, if any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us.

Recent PRC regulations relating to the establishment of offshore special purpose companies by PRC residents may subject our PRC resident shareholders to personal liability, limit our ability to inject capital into our PRC subsidiaries, limit our PRC subsidiaries ability to distribute profits to us, or otherwise adversely affect us.

The PRC State Administration of Foreign Exchange, or the SAFE, issued a public notice in October 2005, requiring PRC residents to register with the local SAFE branch before establishing or controlling any company outside of China for the purpose of capital financing with assets or equities of PRC companies, referred to in the notice as an offshore special purpose company. PRC residents that are shareholders of offshore special purpose companies established before November 1, 2005 were required to register with the local SAFE branch before March 31, 2006. Our current beneficial owners who are PRC residents have registered with the local SAFE branch as required under the SAFE notice. The failure of these beneficial owners to timely amend their SAFE registrations pursuant to the SAFE notice or the failure of future beneficial owners of our company who are PRC residents to comply with the registration procedures set forth in the SAFE notice may subject such beneficial owners to fines and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, limit our PRC subsidiaries ability to distribute dividends to our company or otherwise adversely affect our business. In addition, the SAFE notice also provides that PRC residents who are shareholders of offshore special purpose companies are required to apply for registration or file with the SAFE within 30 days after the occurrence of certain events with respect to such offshore purpose companies, including the increase or decrease in the registered share capital, the share transfer or exchange of stock rights, acquisition or division, long-term investment of equity or debt, guarantees provided to other parties, provided that such events do not involve direct investment of capital into PRC subsidiaries by those PRC residents through the offshore special purpose companies.

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Our financial results benefit from tax concessions granted by the PRC government, the change to or expiration of which would materially change our results of operations.

Our results of operation may be adversely affected by changes to or expiration of tax holidays and preferential tax policies that some of our PRC subsidiaries currently enjoy. Effective from January 1, 2008, the statutory tax rate generally applicable to Chinese companies is 25%. As a result of tax holidays and preferential tax policies, our operations have been subject to relatively low tax liabilities. For additional details regarding these tax incentives, please see Item 5. Operating and Financial Review and Prospects Taxation and Incentives.

Tax laws in China are subject to interpretations by relevant tax authorities. The preferential tax policies may not remain in effect or may change, in which case we may be required to pay the higher income tax rate generally applicable to Chinese companies, or such other rate as is required by the laws of China.

Dividends we receive from our operating subsidiaries located in the PRC may be subject to PRC withholding tax.

On March 16, 2007, the National People s Congress passed the Corporate Income Tax Law of the PRC, or the new CIT law. The new CIT law provides that a maximum income tax rate of 20% may be applicable to dividends payable to non-PRC investors that are non-resident enterprises, to the extent such dividends are derived from sources within the PRC, and the State Council has reduced such rate to 10% through the implementation rules for the new CIT law. We are a Cayman Islands holding company and State Good Group Limited, or SGG, is a British Virgin Islands intermediate holding company. Substantially all of our income may be derived from dividends we receive from our operating subsidiaries located in the PRC. Thus, dividends paid to us by our subsidiaries in China, if any, may be subject to the 10% income tax if SGG is considered as a non-resident enterprise under the new CIT law. If SGG is required under the new CIT law to pay income tax for any dividends we receive from our subsidiaries, it will materially and adversely affect the amount of dividends, if any, we may pay to our shareholders and ADS holders.

We may be deemed a PRC resident enterprise under the new CIT law and be subject to the PRC taxation on our worldwide income.

The new CIT law also provides that enterprises established outside of China whose de facto management bodies are located in China are considered resident enterprises and are generally subject to the uniform 25% corporate income tax rate as to their worldwide income. Under the implementation rules for the new CIT law issued by the PRC State Council, de facto management body is defined as a body that has material and overall management and control over the manufacturing and business operations, personnel and human resources, finances and treasury, and acquisition and disposition of properties and other assets of an enterprise. Although substantially all of our operational management is currently based in the PRC, it is unclear whether PRC tax authorities would require (or permit) our overseas registered entities to be treated as PRC resident enterprises. If we are treated as resident enterprises for PRC tax purposes, we will be subject to PRC tax on our worldwide income at the 25% uniform tax rate, which could have an impact on our effective tax rate and an adverse effect on our net income and results of operations, although dividends distributed from our PRC subsidiaries to us could be exempt from Chinese dividend withholding tax, since such income is exempt under the new CIT law to PRC resident recipients.

Dividends payable by us to our foreign investors and gain on the sale of our ADSs or ordinary shares may become subject to taxes under PRC tax laws.

Under the new CIT law and the implementation rules issued by the State Council, PRC income tax at the rate of 10% is applicable to dividends payable to investors that are non-resident enterprises , which do not have an establishment or place of business in the PRC, or which have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends have their sources within the PRC. Similarly, any gain realized on the transfer of ADSs or ordinary shares by such investors is also subject to 10% PRC income tax if such gain is regarded as income derived from sources within the PRC. If we are considered a PRC resident enterprise , it is unclear whether dividends we pay with respect to our ordinary shares or ADSs, or the gain you may realize from the transfer of our ordinary shares or ADSs, would be treated as income derived from sources within the PRC and be subject to PRC income tax. If we are required under the new CIT law to withhold PRC income tax on dividends payable to our non-PRC investors that are non-resident

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enterprises , or if you are required to pay PRC income tax on the transfer of our ordinary shares or ADSs, the value of your investment in our ordinary shares or ADSs may be materially and adversely affected.

Fluctuation in the value of the Renminbi may have a material adverse effect on your investment.

The change in value of the Renminbi against the U.S. dollar, Euro or other currencies is affected by, among other things, changes in China s political and economic conditions. On July 21, 2005, the PRC government changed its decade-old policy of pegging the value of the Renminbi to the U.S. dollar. Under the new policy, the Renminbi is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies.

There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which could result in a further and more significant appreciation of the Renminbi against the U.S. dollar. As we rely on dividends paid to us by our operating subsidiaries, any significant revaluation of the Renminbi may have a material adverse effect on the value of, and any dividends payable on, our ADSs in foreign currency terms. Appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we would receive from the conversion. Conversely, if we decide to convert our Renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the Renminbi would have a negative effect on the U.S. dollar amount available to us. In addition, appreciation or depreciation in the value of the Renminbi relative to the U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations.

Governmental control of currency conversion may affect the value of your investment.

The PRC government imposes controls on the convertibility of the Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. We receive all our revenues in Renminbi. Under our current corporate structure, our income is primarily derived from dividend payments from our PRC subsidiaries. Shortages in the availability of foreign currency may restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency-denominated obligations. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and expenditures from trade related transactions, can be made in foreign currencies without prior approval from the SAFE by complying with certain procedural requirements. In addition, foreign currencies received under current account items can be retained or sold to financial institutions engaged in the foreign exchange settlement or sales business by complying with relevant regulations. However, approval from SAFE or its local branch is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. Similarly, approval from the SAFE or its local branch is required if foreign currencies received in respect of capital account items is to be retained or sold to financial institutions engaged in the foreign exchange settlement or sales business. The PRC government may also, at its discretion, restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of our ADSs.

We face risks related to health epidemics and other outbreaks of contagious diseases, including avian flu, SARS, and swine flu.

Our business could be adversely affected by the effects of avian flu, SARS, swine flu or another epidemic or outbreak. During April and May 2009, there have been outbreaks of highly pathogenic swine flu, caused by the H1N1A virus, in certain regions of the world, including parts of Asia. In 2007 and early 2008, there were reports of outbreaks of a highly pathogenic avian flu, caused by the H5N1 virus, in certain regions of Asia and Europe. In 2005 and 2006, there were reports on the occurrences of avian flu in various parts of China, including a few confirmed human cases. An outbreak of avian flu in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, particularly in Asia. Additionally, any recurrence of SARS, a highly contagious form of atypical pneumonia, similar to the occurrence in 2003 which affected China, Hong Kong, Taiwan, Singapore, Vietnam and certain other countries, would also have similar adverse effects. These outbreaks of contagious diseases, and other adverse public health developments in China,

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would have a material adverse effect on our business operations. These could include restrictions on our ability to travel or to ship our products within China, as well as cause temporary closure of our manufacturing facilities. Such closures or travel or shipment restrictions would severely disrupt our business operations and adversely affect our financial condition and results of operations. We have not adopted any written preventive measures or contingency plans to combat any future outbreak of avian flu, SARS, swine flu or any other epidemic.

Risks Related to Our ADSs

The market price for our ADSs may be volatile.

The market price for our ADSs is likely to be highly volatile and subject to wide fluctuations in response to factors including the following:

announcements of technological or competitive developments;

regulatory developments in China affecting us, our customers or our competitors;

announcements regarding patent litigation or the issuance of patents to us or our competitors;

actual or anticipated fluctuations in our quarterly operating results;

changes in financial estimates by securities research analysts;

changes in the economic performance or market valuations of other pharmaceutical companies;

addition or departure of our executive officers and key research personnel;

release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; and

sales or perceived sales of additional ordinary shares or ADSs.

In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also have a material adverse effect on the market price of our ADSs.

Substantial future sales or perceived sales of our ADSs in the public market could cause the price of our ADSs to decline.

Future sales of our ADSs or ordinary shares in the public market or the perception that these sales could occur, may cause the market price of our ADSs to decline. As of May 31, 2009, we have issued 118,931,380 ordinary shares, including 116,926,380 ordinary shares outstanding and 2,005,000 ordinary shares issued to The Bank of New York Mellon which were held on behalf of us for future exercise of share options. All ADSs sold are freely transferable without restriction or additional registration under the Securities Act of 1933, as amended, or the Securities Act.

In addition, Assure Ahead Investment Limited or its transferees and assignees and King View Development International Limited or its transferees and assignees will have the right to cause us to register the sale of their shares under the Securities Act upon the occurrence of certain circumstances. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. Sales of these registered shares in the public market could cause the price of our ADSs to decline.

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Our articles of association contain anti-takeover provisions that could discourage a third party from acquiring us, which could limit our shareholders opportunity to sell their shares, including ordinary shares represented by our ADSs, at a premium.

Our second amended and restated articles of association currently in effect limit the ability of others to acquire control of our company or cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transaction. For example, our board of directors has the authority, without further action by our shareholders, to issue preferred shares. These preferred shares may have better voting rights than our ordinary shares, in the form of ADSs or otherwise, and could be issued quickly with terms calculated to delay or prevent a change in control of our company or make removal of management more difficult. If our board of directors decides to issue preferred shares, the price of our ADSs may fall and the voting rights of the holders of our ordinary shares and ADSs may be diluted.

Certain actions require the approval of a supermajority of at least two-thirds of our board of directors which, among other things, would allow our non-independent directors to block a variety of actions or transactions, such as a merger, asset sale or other change of control, even if all of our independent directors unanimously voted in favor of such action, thereby further depriving our shareholders of an opportunity to sell their shares at a premium.

Holders of ADSs have fewer rights than shareholders and must act through the depositary to exercise those rights.

Holders of ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Under our second amended and restated memorandum and articles of association, the minimum notice period required to convene a general meeting is seven days. When a general meeting is convened, you may not receive sufficient notice of a shareholders meeting to permit you to withdraw your ordinary shares to allow you to cast your vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ADSs.

Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you requested. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders meeting.

You may be subject to limitations on transfers of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deem it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings and you may not receive cash dividends if it is impractical to make them available to you.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act, or exempted from registration under the Securities Act. We are under no obligation to file a registration statement with

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respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

In addition, the depositary of our ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary may, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of ADSs. For example, the depositary may determine that it is not practicable to distribute certain property through the mail, or that the value of certain distributions may be less than the cost of mailing them. In these cases, the depositary may decide not to distribute such property and you will not receive such distribution.

We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than that under U.S. law, you may have less protection for your shareholder rights than you would under U.S. law.

Our corporate affairs are governed by our second amended and restated memorandum and articles of association, the Cayman Islands Companies Law (as amended) and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as that from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. In addition, some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as shareholders of a U.S. public company.

You may have difficulty enforcing judgments obtained against us.

We are a Cayman Islands company and substantially all of our assets are located outside of the United States. Substantially all of our current operations are conducted in the PRC. In addition, most of our directors and officers are nationals and residents of countries other than the United States. As a result, it may be difficult for you to effect service of process within the United States upon these persons. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors, most of whom are not residents in the United States and the substantial majority of whose assets are located outside of the United States. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state and it is uncertain whether such Cayman Islands or PRC courts would be competent to hear original actions brought in the Cayman Islands or the PRC against us or such persons predicated upon the securities laws of the United States or any state. See Enforcement of Civil Liabilities.

Item 4. Information of the Company

A. History and Development of the Company

Our predecessor entity, Hainan Simcere Investment Group Ltd., or Simcere Investment, was a PRC company that held a group of pharmaceutical companies that develops, manufactures and markets a range of branded generic and innovative pharmaceuticals. To raise capital from investors outside of China, we established State Good Group Limited, or SGG, in the British Virgin Islands on October 12, 2005. Our operating subsidiaries

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were transferred to SGG in March 2006 as part of a series of corporate reorganization activities. We incorporated Simcere Pharmaceutical Group in the Cayman Islands as a listing vehicle on August 4, 2006. Simcere Pharmaceutical Group became our ultimate holding company when it issued ordinary shares to existing shareholders of SGG on September 29, 2006, in exchange for the respective ordinary shares that these shareholders held in SGG.

Subsequent to our initial public offering on April 20, 2007, we have engaged in several acquisitions to strengthen our product portfolio, especially as to first-to-market generic and innovative pharmaceuticals in China. We have acquired the remaining 20.0% equity interest in Shandong Simcere that we did not own at the time of our initial public offering and as a result, Shandong Simcere is now our wholly owned subsidiary. In October 2007, we completed the acquisition of a 51.0% equity interest in Jilin Boda. In November 2007, we acquired 100% equity interest in Master Luck Corporation Limited, which in turns holds an 85.71% equity interest in Nanjing Tung Chit, the manufacturer of nedaplatin injection, a chemotherapy pharmaceutical that is marketed under the brand name Jiebaishu. Furthermore, in April 2008, we acquired a 70.0% equity interest in Wuhu Simcere Zhong Ren for a cash consideration of approximately RMB65.1 million ($9.5 million). Wuhu Simcere Zhong Ren is a pharmaceutical manufacturer based in the PRC specializing in the production of antineoplastic implants. These transactions are accounted for using the purchase method of accounting in our consolidated financial statements. Accordingly, the assets and liabilities acquired by us have been recognized at their respective fair values on the date of acquisition.

In May 2009, we entered into an agreement to indirectly acquire approximately 35% of the equity interest of Shanghai Celgen Bio-Pharmaceutical Co., Ltd., or Shanghai Celgen for a total cash consideration of RMB140.0 million. Shanghai Celgen has strong expertise in research and production of therapeutic antibodies and possesses an antibody manufacturing facility in Shanghai, for which GMP certification is pending. Shanghai Celgen s major biogeneric drug candidate, an etanercept, has completed clinical trials and is currently awaiting approval from the SFDA. In addition, we are entitled to unwind the acquisition and the selling shareholders are required to return the amounts paid by us if the SFDA does not approve Shanghai Celgen s major biogeneric drug candidate within 24 months from the date of agreement. The agreement is subject to certain closing conditions.

In May 2009, we entered into an agreement to acquire a 37.5% equity interest in Jiangsu Yanshen Biological Technology Stock Co., Ltd., or Jiangsu Yanshen, a China-based developer and manufacturer of vaccines, from existing shareholders for a total cash consideration of approximately RMB195.5 million. Jiangsu Yanshen s core products include an influenza vaccine and a human use rabies vaccine (vero cell). Upon the closing of the transaction, we are expected to be the largest shareholder in Jiangsu Yanshen. Jiangsu Yanshen has received a new medicine certificate from the SFDA for its freeze-dried human use rabies vaccine (vero cell) and has completed clinical trials of its purified hepatitis A inactivated vaccine (vero cell). SFDA approval for the purified hepatitis A inactivated vaccine (vero cell) and GMP certification for the associated new manufacturing facility are pending.

B. Business Overview

We are a leading manufacturer and supplier of branded generic pharmaceuticals in the fast growing China market. We focus our strategy on the development of first-to-market generic and innovative pharmaceuticals, and have introduced a first-to-market generic anti-stroke medication under the brand name Bicun, a 5-FU sustained release implant under the brand name Sinofuan, and an innovative anti-cancer medication under the brand name Endu. We currently manufacture and sell 45 principal pharmaceutical products and are the exclusive distributor of three additional pharmaceuticals that are manufactured by independent third parties but marketed under our brand names. In addition, we have obtained approvals from the SFDA to manufacture and sell over 220 other products. As of March 31, 2009, we also had 12 product candidates in various stages of development, including treatments for cancer, cerebrovascular diseases, infections, rheumatoid arthritis, nausea and vomiting associated with chemotherapy.

Our innovative anti-cancer medication Endu has been granted an invention patent in China and was the first recombinant human endostatin injection approved for sale in China. Recombinant human endostatin is a genetically engineered protein that interferes with the growth of blood vessels to a tumor, thereby starving and preventing the growth of tumor cells. Our generic anti-stroke medication Bicun was the first edaravone injection, a type of neuroprotective pharmaceutical compound, approved for sale in China. Our generic amoxicillin granule antibiotic, marketed under the brand name Zailin, was recognized as a China Well-Known Trademark in 2004 and our anti-inflammatory pain relievers and analgesic drug for the treatment of rheumatoid arthritis and osteoarthritis,

marketed

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under the brand name Yingtaiqing, was recognized as a China Well-Known Trademark in 2008. Furthermore, our medication Sinofuan, a sustained release implants for the treatment of cancer which we acquired through our acquisition of Wuhu Simcere Zhong Ren, was the first sustained-released fluorouracil implant approved by the SFDA, and our generic anti-infection medication Anxin, a new product that we introduced in 2008, was the first biapenem injection, a type of carbapenem, approved for sale in China.

We commenced operations in March 1995 as a distributor of pharmaceutical products, and since then we have established an extensive distribution network in China that we now use to market, sell and distribute our own pharmaceutical products. We sell our products exclusively to regional distributors, who then sell them to local distributors, hospitals and retail pharmacies throughout China. Our marketing team leverages the reputation of our Simcere brand name and our well-known branded pharmaceuticals to cross-sell our other pharmaceuticals. We also have dedicated brand management, market research and sales support teams to further enhance the effectiveness of these marketing efforts.

We employ a market-oriented approach to research and development and focus our efforts on branded generic pharmaceuticals that have the potential for gaining widespread market acceptance or are the first generic version on the market. We concentrate our research and development efforts on the treatment of diseases with high incidence and/or mortality rates and for which there is a clear demand for more effective pharmacotherapy, such as cancer and cerebrovascular and infectious diseases. Through our research and development efforts, we have introduced to the China market a sizable portfolio of branded products with significant market potential.

Our Products

We currently manufacture and sell 45 principal pharmaceuticals marketed under various brands. Of these products, 36 are prescription pharmaceuticals and nine are over-the-counter, or OTC, pharmaceuticals. In addition, we are also the exclusive distributor of Yingtaiqing-branded generic diclofenac sodium sustained-release capsules, the Faneng-branded generic alfacalcidol soft capsules and the Yineng-branded generic lentinan injection, all of which are prescription pharmaceuticals manufactured by independent third parties. Furthermore, we have obtained approvals from the SFDA to manufacture and sell over 220 other products.

The following table sets forth the major treatment areas by our current principal products, the number of products for each treatment area and the brands they are marketed under:

Product Category	Number of Products	Major Products	Brands
Antibacterial and Antiviral	16	Amoxicillin granules, capsules and tablets ; Amoxicillin with clavulanate potassium granules, tablets and injection; biapenem injection; cefaclor dry suspension; azithromycin granules; and ribavirin dispersible tablets	Zailin, Anqi, Anxin, Zaike, Zaiqi and Nanyuan
Anti-cancer	5	Recombinant human endostatin injection, nedaplatin injection, lentinan injection and fluorouracil implants	Endu, Jiebaishu, Yineng and Sinofuan
Anti-Allergic	2	Clemastine fumarate capsules and clemastine fumarate dry suspension	Langjing
Anti-Osteoporosis	2	Alfacalcidol soft capsules	Faneng
Cardiovascular and Cerebrovascular	5	Edaravone injection; amlodipine maleate tablets; and sumatriptan succinate tablets	Bicun, Yidasheng, Ningliping and Youshu
Digestive Conditions	3	Smectite powder and aldioxa tablets	Biqi and Odijia
Non-Steroidal Anti-Inflammatory	2	Diclofenac sodium sustained-release capsules and gelatin	Yingtaiqing

Respiratory System	6	Herbal medicine used for the treatment of cough in liquids and tablets; artificial cowbezoar and chlorphenamine maleate granules compound paracetamol and amantadine hydrochloride tablets; compound zinc gluconate; pediatric paracetamol;	Simcere Kechuanning, Zaikang, Boke, Aiersi and Boting
Urinary Conditions	1	Naftopidil tablets	Zaichang
Others	3	Various herbal oral solutions	Chengyuan and Shibo

Our Innovative Pharmaceutical Endu (Recombinant Human Endostatin Injection)

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Our innovative pharmaceutical Endu, or recombinant human endostatin, has been granted an invention patent in China and was the first recombinant human endostatin injection approved for manufacture and sale in China and has been approved for the treatment of NSCLC. Recombinant human endostatin is a genetically engineered protein that interferes with the growth of blood vessels to a tumor, thereby starving and preventing the growth of tumor cells. In 2008, revenues of Endu amounted to RMB239.4 million ($35.1 million) which accounted for 13.8% of our product revenues for the year.

The treatment of cancer by disrupting a tumor s blood supply has been under research since the 1970s. In February 2004, the U.S. Food and Drug Administration approved Avastin, an anti-cancer drug based on this principle. Shortly before Avastin s approval, a U.S. based pharmaceutical company stopped its clinical research of a drug called endostatin, a broad spectrum antiangiogenic protein, citing high manufacturing costs. Endu is a modified version of endostatin that was developed by a team of scientists led by Dr. Yongzhang Luo and Dr. Bin Zhou, both of whom received doctorate degrees in biochemistry from the University of California at Berkeley. Endu has been engineered to contain an additional nine-amino acid sequence to enhance protein purification, solubility and stability and has been shown to improve the function of endostatin. Endu exhibits low toxicity in humans based on clinical trials conducted between 2001 and 2004 on 493 Chinese patients with NSCLC.

These clinical trials showed that the median survival time of the Endu group was approximately five months longer than that of the control group and one year survival rates of the Endu group was 62.8% compared to 31.5% for the control group. The SFDA granted the new medicine certificate for Endu in September 2005 and the relevant approvals to manufacture and sell Endu in March 2006 to Shandong Simcere, a pharmaceutical company founded by Dr. Luo that held an invention patent in China on Endu granted on January 18, 2006.

We entered into an agreement to acquire an 80.0% equity interest in Shandong Simcere in May 2006. As a result of the acquisition, we have obtained the exclusive right to manufacture Endu and hold the invention patent in China for Endu. We also hold one invention patent in the United States covering N-terminal modified recombinant human endostatin and its production. Prior to the completion of our acquisition of Shandong Simcere, we began to market and sell Endu in July 2006 as the exclusive distributor for Shandong Simcere. Upon completion of the acquisition in September 2006, we also began to manufacture Endu in China. In June 2007, we acquired an additional 10.0% equity interest in Shandong Simcere. In January 2009, we acquired the remaining 10.0% equity interest in Shandong Simcere which is now our wholly owned subsidiary.

We have an in-house research and development team specializing in anti-cancer drugs, know-how and technologies that will enable us to engage in research and development of other indications for Endu, and an existing GMP-approved manufacturing facility for the production of Endu. As part of our ongoing efforts to monitor the efficacy and any adverse reactions to Endu, we are currently conducting Phase IV clinical trials for Endu in approximately 150 hospitals in China in which over 2,400 patients have enrolled in the trials. We are also engaged in various research and development efforts to maximize the commercial potential of Endu. For example, we are also researching other potential indications for Endu as well as on expanding the scope of use for Endu outside of chemotherapy. In addition, we are working to improve the delivery method of Endu for increased ease of use.

Hong Kong Medgenn has the exclusive right to engage in the development and sale of Endu in any jurisdiction outside of the PRC, including the United States, until February 10, 2015. Hong Kong Medgenn also holds the rights to apply for patents outside of the PRC and may grant its rights with respect to Endu in these jurisdictions to independent third parties. We hold indirectly an effective 40.0% equity interest in Hong Kong Medgenn. See Item 3. Key Information D. Risk Factors Risks Related to our Company We have no control over the development and sale of Endu outside of the PRC. Our brand and reputation may be adversely affected if the development and sale of Endu outside of the PRC violates the intellectual property rights of any third parties.

Our Principal Branded Generic Pharmaceuticals

We currently market and sell the following principal branded generic pharmaceutical products, each of which contribute over RMB100.0 million ($14.7 million) to our revenues in 2008 and in aggregate accounted for 58.0% of our product revenues in 2008:

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Bicun (edaravone injection);

Zailin (amoxicillin capsules, dispersible tablets, granules and injection); and

Yingtaiqing (diclofenac sodium sustained-release capsules and gelatin).

Bicun. Bicun is our prescription edaravone injection pharmaceutical for the treatment of strokes. Edaravone is a synthetic free radical scavenger and has been proved to be one of the most effective neuroprotective pharmaceuticals, as evidenced by being recommended as the only neuroprotective agent by the Japan Stroke Therapeutic Guide (2004). Edaravone protects the brain by eliminating excessive free radicals, which are highly reactive molecules occurring in the human body as a result of stroke, an excessive number of which could result in cell damage. Bicun was the first edaravone injection approved for sale in China and has been one of our major products since its introduction in China in February 2004. We obtained regulatory approval to manufacture and sell Bicun in December 2003. The monitoring period of Bicun expired in 2007 and a number of competitors have been entered into the edaravone injection market. In 2008, revenues of Bicun amounted to RMB570.6 million ($83.6 million), which accounted for 32.9% of our product revenues for the year.

Zailin. Zailin is the brand name for our line of generic prescription amoxicillin antibiotics, which includes capsules, dispersible tablets, granules and injection. Zailin was recognized as a China Well-Known Trademark by the PRC Trademark Office of the State Administration for Industry and Commerce in 2004 and is one of only two antibiotic brands in China granted such recognition. Regulatory approvals to manufacture and sell Zailin granules were obtained in February 1993, Zailin capsules in October 1996, Zailin tablets in June 1998 and Zailin injection in July 2001. Amoxicillin has been included in the national Medical Insurance Catalog since 2000. In 2008, revenues of Zailin amounted to RMB290.2 million ($42.5 million), which accounted for 16.7% of our product revenues for the year.

Yingtaiqing. Yingtaiqing is the brand name for our generic diclofenac sodium in sustained-release capsules and gelatin dosage format, which is an anti-inflammatory pain reliever and analgesic drug used to treat rheumatoid arthritis and osteoarthritis. Yingtaiqing sustained-release capsules are prescription pharmaceuticals and are currently manufactured by a third-party manufacturer, the China Pharmaceutical University Pharmaceutical Company, or China Pharmaceutical, and we have entered into an exclusive distribution agreement with China Pharmaceutical to distribute and sell Yingtaiqing sustained-release capsules in China since 1996. A master distribution agreement was renewed in December 2008. Pursuant to the master distribution agreement, we have agreed to purchase from China Pharmaceutical a certain minimum quantity of Yingtaiqing sustained-release capsules in 2009. We obtained the regulatory approval to manufacture and sell Yingtaiqing gelatin, an OTC medicine, in December 2005. Yingtaiqing was recognized as a China Well-Known Trademark in 2008. Diclofenac sodium has been included in the national Medical Insurance Catalog since 2000. In 2008, sales of Yingtaiqing amounted to RMB146.7 million ($21.5 million), which accounted for 8.4% of our product revenues for the year.

Other Branded Generic Pharmaceutical Products

In addition to Endu and our three principal products, the following branded generic pharmaceutical products in aggregate also represent a significant portion of our revenues, and accounted in aggregate for 19.2% of our product revenues in 2008.

Sinofuan. Sinofuan is our first-to-market sustained release implants for the treatment of cancer. In April 2008, we acquired Sinofuan by acquiring a 70.0% equity interest of Wuhu Simcere Zhong Ren.

Yidasheng. Yidasheng is our prescription edaravone injection pharmaceutical for the treatment of strokes. Yidasheng became our product in October 2007, when we completed the acquisition of a 51.0% stake in Jilin Boda, the manufacturer of Yidasheng.

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Biqi. Biqi is the brand name for our generic OTC anti-diarrhea pharmaceutical. We obtained regulatory approval to manufacture and sell Biqi in November 1999. Biqi has been included in the national Medical Insurance Catalog since 2000.

Anqi. Anqi is the brand name of our amoxicillin and clavulanate potassium tablets, granules, and injection for the treatment of infections.

Zaike. Zaike is the brand name for our cefaclor in dry suspension antibiotics for the treatment of infections. Regulatory approval to manufacture and sell Zaike was obtained in February 1995. Zaike has been included in the national Medical Insurance Catalog since 2000.

Simcere Kechuanning. Simcere Kechuanning is the brand name for our OTC herbal medicine used for the treatment of coughs. It comes in oral liquid and tablet formulations. Regulatory approvals to manufacture and sell Simcere Kechuanning oral liquids were obtained in October 1995 and tablets in March 2004. Simcere Kechuanning has been included in the national Medical Insurance Catalog since 2000.

Marketing and Distribution

We have over a decade of marketing experience in the pharmaceutical industry in China. From our inception in March 1995 to 2001, we operated as a distributor of pharmaceuticals and have leveraged our experience to establish an extensive distribution network in China that we now use to market, sell and distribute our own pharmaceuticals. As of December 31, 2008, we had 963 dedicated brand management and marketing employees. Our marketing and distribution activities are primarily carried out by our subsidiaries, Jiangsu Simcere and Shanghai Simcere.

Our Marketing Strategy

We have established a fully integrated marketing strategy that includes brand management, market research and liaising with various levels of regulatory authorities and government institutions. We host in-person product presentations, conferences and seminars for physicians, other healthcare professionals and research scholars to promote and generate awareness of our pharmaceuticals, and to facilitate discussion between medical and pharmaceutical professionals in China regarding our pharmaceuticals. We also have a dedicated marketing division that is in charge of our overall marketing strategy, our branding efforts and our market research efforts. To support our marketing strategy, we plan to continue expanding our own internal marketing force.

In addition, for our OTC pharmaceuticals, we also engaged in consumer advertising and educational campaigns on television, newspapers, magazines, billboards and sponsorship of charitable events in 2008. We believe competition in the OTC market is primarily based on brand awareness, pricing and the therapeutic value of the pharmaceuticals. Furthermore, we have also set up a toll-free hotline to respond to end-users questions regarding our OTC pharmaceuticals.

Our marketing professionals collect feedback from healthcare professionals, pharmacies and end-users regarding our products. Our marketing professionals then work closely with our research and development department and manufacturing department in order to enhance our existing portfolio of pharmaceuticals and to identify potential new products for commercialization.

Distribution

We sell all of our products to pharmaceutical distributors in China. We have business relationships directly or indirectly with approximately 1,700 pharmaceutical distributors in China. Each pharmaceutical distributor in turn may distribute our pharmaceuticals within a designated region either directly to hospitals, clinics, pharmacies and other retail outlets or to local distributors. Our products are sold to hospitals and retail pharmacies throughout China. Many of our pharmaceuticals are widely distributed in large hospitals located in some of the most prosperous regions in China.

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We select our distributors based on their reputation, market coverage, sales experience and the size of their marketing and distribution force. We typically enter into written distribution agreements with our regional distributors for one-year terms that are generally renewed annually. These distribution agreements set out the targeted quantities and prices for our pharmaceuticals, as well as guidelines for the sale and distribution of our products, including restrictions on the territories in which the products may be sold. We believe that each of our target customer groups is important to our business and we will continue to seek opportunities for sales growth in each group.

Our distributors are widely dispersed on a geographic basis. Each distributor is limited to its respective designated distribution areas as specified in our distribution agreements. In each of 2006, 2007 and 2008, no single distributor contributed to, on an individual basis, 10.0% or more of our total revenues, and sales to our five largest distributors accounted in aggregate for approximately 12.7%, 13.8% and 11.6%, respectively, of our product revenues.

We have limited ability to manage the activities of our distributors, who are independent from us. Our distributors may potentially engage in actions that may violate the anti-corruption laws in China, engage in other illegal practices or exhibit and damaging behaviors with respect to their sales or marketing of our products, which could have a material adverse effect on our business, prospects and brand. For additional information, see Item 3. Key Information D. Risk Factors Risks Related to Our Company We may not be able to effectively manage our employees, distribution network and third-party marketing firms, and our reputation, business, prospects and brand may be materially and adversely affected by actions taken by our distributors.

Manufacturing, Quality Control and Supplies

Manufacturing

We currently have six GMP-approved manufacturing facilities in China located in Jiangsu, Hainan, Shandong, Jilin and Anhui Provinces. We also own the mining right of a smectite mine, located in Sichuan Province. See Facilities. In addition, three of our generic pharmaceuticals, the Yingtaiqing-branded diclofenac sodium capsules, the Faneng-branded alfacalcidol soft capsules and the Yineng-branded lentinan injection, are manufactured by independent third-party manufacturers.

A portion of our production lines are equipped with automated machinery and equipment and can be used to produce different kinds of pharmaceuticals in the same physical dosage form without the need to significantly modify the current production facilities and equipment. We therefore are able to adjust our production to meet market demand and our sales target in response to market demand. The following table is a summary of our 2008 production capacity:

Pharmaceutical Agent Production Unit	Delivery Form	2008 Capacity
Hainan Simcere		
Penicillin family	Granules	630,000,000 packs
Penicillin family	Capsules	378,000,000 pills
Cefaclor family	Granules	240,000,000 packs
Cefaclor family	Capsules	12,000,000 pills
Cefaclor family	Tablets	140,000,000 pills
General	Tablets	80,000,000 pills
General	Granules	360,000,000 packs
General	Gelatin	10,000,000 tubes
General	Powder	180,000,000 packs
General	Capsules	360,000 pills
Nanjing Simcere		
Penicillin family	Powder injection	8,400,000 vials
Penicillin family	Granules	41,904,000 packs
Penicillin family	Dry suspension	65,000,000 bottles
Penicillin family	Tablets	64,440,000 pills

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Pharmaceutical Agent Production Unit	Delivery Form	2008 Capacity
General	Oral solution	28,800,000 bottles
General	Small volume parenteral solutions	18,000,000 vials
General	Tablets	20,640,000 packs
General	Dry suspension	27,600,000 packs
General	Capsules	72,000,000 pills
General	Granules	20,000,000 packs
General	Powder injection	7,500,000 vials
General	Frozen-dry powder	3,200,000 vials
General	Sterile active pharmaceutical ingredients, or APIs	420 kg
Shandong Simcere		
Recombinant human endostatin	Injection	1,000,000 vials
Nanjing Tung Chit		
Nedaplatin injection	Frozen-dry powder injection	600,000 bottles
Jilin Boda		
Edavarone injection	Low-dose injection	10,000,000 vials
General	Tablets	800,000,000 pills
General	Capsules	300,000,000 pills
General	Granules	100,000,000 packs
General	Topical solution	5,000,000 bottles
General	Powder injection	1,500,000 packs
APIs	Moroxydine	1,000,000 kg
APIs	Asparamide	100,000 kg
APIs	Ethacridine lactate	5,000 kg
APIs	Nefopam hydrochloride	5,000 kg
APIs	Edaravone	60,000 kg
Wuhu Simcere Zhong Ren		
Fluorouracil implant	Implant	1,000,000 vials

Quality Control

Our senior management team is actively involved in setting internal quality control policies and monitoring our product quality control process. Our quality control team is responsible for the testing of our pharmaceuticals to ensure that we comply with all applicable regulations, standards and internal policies during the manufacturing process. We carry out quality control procedures in compliance with GMP standards and SFDA regulations and in accordance with our internal policies with a view towards ensuring the consistency and high quality of our products. We inspect and test packaging materials before manufacturing and test intermediate products based on various criteria, such as physical appearance (including the shape of capsules and granules), cleanliness, ingredient composition and weight. Once the products are finalized, we conduct final product testing before distributing our products to our distributors.

Raw Materials

The principal raw materials used for our products are the necessary active ingredients of our pharmaceuticals. We source such raw materials, as well as packaging materials, from various independent suppliers in China. In addition, we produce certain active ingredients used for the production of some of our pharmaceutical products, such as Bicun, and we also own the mining rights relating to a smectite mine that produces smectite, a raw material used for the

manufacturing of Biqi. In the case of sourcing raw materials from third parties, the purchase price for the relevant raw materials is based on the prevailing market price for such materials of similar quality. Our principal packaging materials include glass ampules for injection pharmaceuticals, plastic bottles for capsule and tablet pharmaceuticals, and external packaging and printed instructions for all of our pharmaceuticals. In 2008, we purchased an aggregate of 40.3% of our total supply of raw materials from our five largest suppliers.

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Historically, the majority of our raw materials have been readily available. We generally maintain two vendors for each major raw material in order to diversify our vendor base and help to ensure a reliable supply of raw materials at reasonable prices. To date, raw material shortages or price fluctuations have not had any material adverse effect on us. We also maintain a supplier evaluation scheme through which potential vendors are evaluated based on a number of factors including quality, timely delivery, cost and technical capability. In addition, we conduct periodic onsite reviews of our suppliers facilities.

Competition

We face direct competition from pharmaceutical manufacturers producing the same type of pharmaceuticals and indirect competition from pharmaceutical manufacturers producing products having similar medical efficacy as substitutes. Our competitors vary by product:

For Endu, there are currently no directly competitive products as Endu is the first recombinant human endostatin injection approved for sale in China. However, Endu indirectly competes with other types of cancer treatments currently available in China.

For Bicun, the main competitive product was Yidasheng manufactured by Jilin Boda, which we acquired a 51.0% equity interest in October 2007. However, in 2008, three other pharmaceutical companies, China National Medicines Gourui Pharmaceutical Co.,Ltd., Kunming Jida Pharmaceutical Co,. Ltd., and Jilin Huinan Changlong Biopharmaceutical Co., Ltd. launched their edaravone injections in China.

For Zailin, the main competitive products are Amoxian and Amoxilin, which are manufactured by Zhuhai United Laboratories Pharmaceutical Co., Ltd. and Kunming Baker Norton Pharmaceutical Co., Ltd., respectively.

For Yingtaiqing, the main competitive products are Votalin and Difene, which are manufactured by Beijing Novartis Pharma Ltd. and Klinge Pharma GmbH of Germany, respectively.

Our generic pharmaceuticals are not protected by patents and are thus subject to competition from other generic pharmaceuticals. However, the SFDA may at its discretion, subject to certain limitations, grant first-to-market generic pharmaceuticals the protection of a multiple-year monitoring period, or a protection period under the prior regulation, during which other pharmaceutical companies cannot apply for the registration of pharmaceuticals with the same chemical structure, dosage form and indication. See Item 4. Information of the Company B. Business Overview Regulation Approval and Registration of Pharmaceutical Products. Once the transitional protection period elapses, other manufacturers will be able to produce pharmaceuticals with the same chemical structure, dosage form and indication, and may be able to sell such products at a lower price. As a result, hospitals, clinics, pharmacies and other retail outlets may choose the lower priced products over our pharmaceuticals, resulting in a commensurate loss in sales of our products. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business Most of our products are branded generics, which can be manufactured and sold by other pharmaceutical manufacturers in China once the relevant protection or monitoring periods elapse. Furthermore, for our patented pharmaceuticals, the existence of a patent may not necessarily protect us from competition as our patent may be challenged, invalidated or held to be unenforceable. This is because patent applications can take many years to be approved and issued and currently pending applications may later result in issued patents that our product candidates or technologies may infringe. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business The existence of a patent may not necessarily protect us from competition as our patent may be challenged, invalidated or held unenforceable.

The pharmaceutical industry is characterized by rapid product development and technological change. Our pharmaceuticals could be rendered obsolete or made uneconomical by the development of new pharmaceuticals to treat the conditions addressed by our pharmaceuticals, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors. Our business, results of operations and financial condition could be materially adversely affected by any one or more of these developments. Our competitors may also be able to obtain regulatory approval for new products more quickly than we are and, therefore, may begin to

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market their products in advance of our products. We believe that competition among pharmaceuticals in China will continue to be based on, among other things, brand name recognition, product efficacy, safety, reliability, availability, promotional activities and price.

Many of our existing and potential competitors have substantially greater financial, technical, manufacturing or other resources than we do. Our competitors greater size in some cases provides them with a competitive advantage with respect to manufacturing costs because of their economies of scale and their ability to purchase raw materials at lower prices. Many of our competitors may also have greater brand name recognition, more established distribution networks, larger customer bases, or have more extensive knowledge of our customer groups. As a result, they may be able to devote greater resources to the research, development, promotion and sale of their products and respond more quickly to evolving industry standards and changes in market conditions than we can. In addition, certain of our competitors may adopt low-margin sales strategies and compete against us based on lower prices. Furthermore, as a result of China s admission to the WTO in 2001 and subsequent changes in PRC government laws and regulations, we may also face increasing competition from foreign manufacturers in addition to domestic manufacturers. Subsequent to the reduction of import tariffs pursuant to China s WTO obligations, the selling prices in China of imported pharmaceuticals have become more competitive. Also, some foreign pharmaceutical manufacturers have set up domestic production bases in China leading to increasing direct competition.

Environmental Matters

Our operations and facilities are subject to environmental laws and regulations stipulated by the national and the local environment protection bureaus in China. Relevant laws and regulations include provisions governing air emissions, water discharges and the management and disposal of hazardous substances and wastes. The PRC regulatory authorities require pharmaceutical companies to carry out environmental impact studies before engaging in new construction projects to ensure that their production processes meet the required environmental standards. As the PRC legal system continues to evolve, we may be required to make significant expenditures in order to comply with environmental laws and regulations that may be adopted or imposed in the future.

Insurance

We maintain property insurance policies covering our equipment and facilities for losses due to fire, flood and a wide range of other natural disasters. Insurance coverage for our fixed assets other than land amounted to approximately RMB568.9 million as of March 31, 2009. We also maintain insurance policies covering products in transit to our customers. We do not maintain product liability insurance or insurance covering potential liability relating to the release of hazardous materials. In addition, we do not maintain business interruption insurance or key employee insurance for our executive officers as we believe it is not the normal industry practice in China to maintain such insurance. We consider our current insurance coverage to be adequate. However, uninsured damage to any of our manufacturing facilities and buildings or a significant product liability claim could have a material adverse effect on our results of operations. We also maintain directors and officers liability insurance for our directors and officers.

Regulation

Our products are subject to regulatory controls governing pharmaceutical products. As a developer, manufacturer and distributor of pharmaceuticals, we are subject to regulation and oversight by different levels of the food and drug administration in China, in particular, the SFDA. The Law of the PRC on the Administration of Pharmaceuticals, as amended on February 28, 2001, provides the basic legal framework for the administration of the production and sale of pharmaceuticals in China and covers the manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products in China. Its implementation regulations set out detailed implementation rules with respect to the administration of pharmaceuticals in China. We are also subject to other PRC laws and regulations that are applicable to manufacturers and distributors in general.

Pharmaceutical Product Manufacturing

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Permits and Licenses for Pharmaceutical Manufacturers

A manufacturer of pharmaceutical products must obtain a pharmaceutical manufacturing permit from the provincial food and drug administration. This permit, once obtained, is valid for five years and is renewable upon its expiration. This permit must be renewed at least six months before its expiration date. Our current pharmaceutical manufacturing permits for each of Hainan Simcere, Nanjing Simcere, Shandong Simcere, Nanjing Tung Chit, Jilin Boda and Wuhu Simcere Zhong Ren will all expire on December 31, 2010. In addition, as Jilin Boda is currently expanding its facilities which then require it to renew its existing manufacturing permit. We do not believe it will be difficult for us to renew our pharmaceutical manufacturing permit. In addition, before commencing business, a pharmaceutical manufacturer must also obtain a business license from the relevant administration for industry and commerce.

Good Manufacturing Practices

A manufacturer of pharmaceutical products and raw materials must obtain the GMP certification to produce pharmaceutical products and raw materials in China. GMP certification criteria include institution and staff qualifications, production premises and facilities, equipment, raw materials, hygiene conditions, production management, quality controls, product distributions, maintenance of sales records and manner of handling customer complaints and adverse reaction reports. A GMP certificate is valid for five years. The certificate must be renewed at least six months before its expiration date. A manufacturer is required to obtain GMP certificates to cover all of its production operations.

Generally, GMP certificates are valid for five years and we do not believe it will be difficult for us to renew any of our GMP certifications. The following table summarizes the most recent GMP certificates we received for each of our manufacturing facilities:

Certification By Facilities	**Coverage**	**Issue Date**	**Expiration Date**
Hainan Simcere			
	Tablets (Including Cephalosporins), Granules, Capsules, Dry Suspensions (Including Cephalosporins, Penicillin), Soft Capsules, Powders, Gelatin	August 30, 2006	August 29, 2011
	Bulk Drug (Montmorillonite, Aluminium, Dihydroxyallan-toninate, Levamlodipine Besylate, Pamidronate Disodium, Valaciclovir Hydrochloride and Benazepril Hydrochloride)	January 8, 2007	January 7, 2012
	Bulk Drug (Sumatriptan Succinate, Meloxicam, Naftopidil, Edaravone and Sibutramine Hydrochloride)	November 26, 2008	November 25, 2013
	Bulk Drug (Amlodipine Maleate, Cefprozil and Cefteram pivoxil)	November 1, 2005	October 31, 2010
Nanjing Simcere			
	Tablets, Granules, Dry Suspensions (Penicillins)	May 6, 2008	May 5, 2013
	Small Volume Parenteral Solutions,	December 3, 2008	December 2, 2013
	Mixture, Oral Solution	October 27,2008	October 26, 2013
	Powder for Injection	August 6, 2008	August 5, 2013
	Sterile Bulk (Biapenem)	July 21, 2008	July 20, 2013
	Tablets, Capsules, Dry Suspensions	March 30, 2006	March 29, 2011
	Granules	May 11, 2006	May 10, 2011
	Powder for Injection (Penicillin)	April 19, 2006	April 18, 2011
Shandong Simcere			

	Recombinant Human Endostatin Injection (Anti-cancer Drugs)	March 20, 2006	March 19, 2011
Jilin Boda			
	Tablets (with hormones), Capsules, Granules, Power, Tinctures, Topical Solution, Bulk Drug (Ethacridine Lactate, Nefopam Hydrochloride, Moroxydine Hydrochloride, Sulfaguanidinem, Phenytoinum Sodium and povidone lodine)	October 9, 2004	October 8, 2009
	Low-Dose Injection	December 9, 2005	December 8, 2010
	Bulk Drug (Edaravone)	December 12, 2005	December 11, 2010
	Bulk Drug (Asparagine)	December 23, 2006	December 22, 2011
	Tablets, Capsules, Granules	November 28, 2008	November 27, 2013
Nanjing Tung Chit			
	Frozen-Dry Powder Injection (Anti-Cancer Drug) and Bulk Drug (Nedaplatin)	August 18, 2004	August 16, 2009
Wuhu Simcere Zhong Ren			
	Anti-cancer Implants	May 18, 2009	May 17, 2014

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Approval and Registration of Pharmaceutical Products

To apply for approval of manufacturing a pharmaceutical with a national standard, the applicant must submit relevant information and samples of the pharmaceutical prepared in accordance with the relevant national standard to the provincial food and drug administration authority. According to the current Administrative Rules on Drug Registration that came into effect on October 1, 2007, provincial food and drug administration authorities will examine the completeness, standardization and authenticity of an application dossier, and organize inspection of the pilot manufactured drugs. Three consecutive production batches of pharmaceutical samples, collected by provincial food and drug administration authorities, will be examined by the designated drug laboratories. Following their respective assessment and investigation of the application, the provincial food and drug administration authority and the pharmaceutical examination laboratories will produce their respective report to the SFDA. The SFDA shall be responsible for the review of the application dossier and the reports, and then conduct a final assessment of the application to consider whether to approve the registration of the medicine. Upon successful final assessment of the application, the SFDA will issue a medicine registration approval.

If a medicine has not previously been marketed in China, the manufacturer must first obtain a new medicine certificate as well as a medicine registration approval from the SFDA. To register new medicines, pharmaceutical manufacturers must obtain approvals from the SFDA to carry out clinical research. Applicants need to submit relevant pre-clinical study information and other relevant reports to the provincial food and drug administration for review. The provincial food and drug administration will also conduct on-site inspections to collect pharmaceutical samples and appoint specified pharmaceutical examination laboratories to exam such pharmaceutical samples. The pharmaceutical examination laboratories will then issue reports to the SFDA, which will then set up an expert team comprised of pharmaceutical professionals and other specialists to conduct a technical assessment of the proposed new medicine and decide whether clinical research should be commenced.

Following successful completion of clinical research, applicants must submit clinical research information and raw material samples to the provincial food and drug administration and the pharmaceutical examination laboratories appointed by the provincial food and drug administration to apply for approval to manufacture the new medicines. The provincial food and drug administration authority will then examine the completeness, standardization and authenticity of the submission materials and conduct an on-site inspection at the production premises of the applicants. The pharmaceutical examination laboratories appointed by the provincial food and drug administration will then exam three consecutive production batches of pharmaceutical samples collected by the provincial food and drug administration. After investigation and assessment, the provincial food and drug administration authority and the examination laboratories appointed by the provincial food and drug administration authority will produce reports to the SFDA, and the SFDA will review the submission materials and carry out a final review of the application of the subject new medicine. Upon fulfillment of the relevant requirements and approval by the SFDA, the applicants will be granted a new medicine certificate and a medicine approval document. The SFDA will then issue to the applicant the Drug Quality Registration Standards with respect to the registered pharmaceuticals which the manufacturer of such pharmaceuticals must strictly comply with.

Upon granting production approval of a new medicine, the SFDA may set a monitoring period of a maximum of five years to continue monitoring the safety of the medicine, during which the relevant pharmaceutical manufacturing company must regularly review the production technologies employed, monitor the quality, stability, curative effects and unfavorable side-effects of the new medicine, and report to the provincial level food and drug administration authority annually. During such a monitoring period, the SFDA will not accept applications for new medicine certificates for the same medicine by other pharmaceutical companies or approve the sale or import of the same medicine by other pharmaceutical companies, except that, for any other application for the same new medicine that had been approved by the SFDA to undergo clinical trials prior to the granting of a monitoring period, the SFDA may approve the application for sale or import of the new medicine if it meets the relevant requirements and will continue to monitor such new medicine. As a result, the monitoring period in connection with a new medicine can limit the competition encountered by the manufacturer of the new medicine. As of March 31, 2009, we held 47 new medicine certificates that are in effect and have obtained 270 medicine approval documents.

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Pre-clinical Research and Clinical Trials

In order to apply for a new medicine certificate, a pharmaceutical company must conduct a series of pre-clinical research including research on the synthesis technology, extraction methods, physical and chemical nature and purity, pharmaceutical forms, selection of prescriptions, manufacturing technologies, examination methods, quality indicators, stability, pharmacology, toxicology and animal pharmacokinetics of pharmaceuticals. This pre-clinical research should be conducted in compliance with the relevant technological guidelines issued by the SFDA. In particular, the safety evaluation research must be conducted in compliance with the Good Laboratory Practice.

After completion of pre-clinical studies and obtaining the relevant approval from the SFDA, clinical trials are conducted in compliance with the Good Clinical Practice. Clinical trials to be conducted range from Phase I to IV, although under certain circumstances, only Phase II and III or only Phase III clinical trials are required.

Phase I preliminary trial of clinical pharmacology and human safety evaluation studies. The primary objective is to observe the pharmacokinetics and the tolerance level of the human body to the new medicine as a basis for ascertaining the appropriate methods of dosage.

Phase II preliminary exploration on the therapeutic efficacy. The purpose is to assess preliminarily the efficacy and safety of pharmaceutical products on patients within the target indication of the pharmaceutical products and to provide the basis for the design research and dosage tests for Phase III. The design and methodology of research in this phase generally adopts double-blind and random methods with limited sample sizes.

Phase III confirm the therapeutic efficacy. The objective is to further verify the efficacy and safety of pharmaceutical products on patients within the target indication of the pharmaceutical products, to evaluate the benefits and risks and finally to provide sufficient experimental proven evidence to support the registration application of the pharmaceutical products. In general, the trial should adopt double-blind, random methods with sufficient sample sizes.

Phase IV stage of application with research conducted by the applicants themselves after the launch of a new pharmaceutical. The objective is to observe the efficacy and adverse reaction of pharmaceutical products under extensive use, to perform an evaluation of the benefits and risks of the application among ordinary or special group of patients, and to ascertain and improve the appropriate dosage volume for application.

Continuing SFDA Regulation

A manufacturer of pharmaceutical products is subject to continuing regulation by the SFDA. If an approved medicine, its labeling or its manufacturing process is significantly modified, pre-market supplemental approval may be required. A manufacturer of pharmaceutical products is subject to periodic re-inspection and market surveillance by the SFDA to determine compliance with regulatory requirements. If the SFDA sees a reason to enforce its regulations and rules, the agency can institute a wide variety of enforcement actions such as fines and injunctions, recalls or seizure of products, imposition of operating restrictions, partial suspension or complete shutdown of production and criminal prosecution.

An approval of pharmaceutical registration issued by the SFDA will be valid for a period of five years. Within six months prior to expiration, the manufacturer may need to apply for re-registration with the provincial drug administrative authorities. Relevant authorities will review the application and renew the registration for such pharmaceutical if the relevant requirements are fulfilled. For innovative pharmaceuticals, completion of Phase IV clinical trial is required prior to the application for re-registration.

Pharmaceutical Distribution

A distributor of pharmaceutical products must obtain a pharmaceutical distribution permit from the relevant provincial- or designated municipal- or county-level food and drug administration. The grant of such permit is

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subject to an inspection of the distributor s facilities, warehouse, hygiene environment, quality control systems, personnel and equipment. The pharmaceutical distribution permit is valid for five years. In addition, a pharmaceutical distributor needs to obtain a business license from the relevant administration for industry and commerce prior to commencing its business.

The most recent pharmaceutical distribution permits obtained by our subsidiaries, Shanghai Simcere and Jiangsu Simcere, for wholesale and retail business operations were issued on December 20, 2004 and July 16, 2007, respectively, and we do not believe it would be difficult for us to renew these certifications.

Restrictions on Foreign Ownership of Pharmaceutical Wholesale and Retail Businesses in China

The Administration Rules on Foreign Investment in Commercial Domains and the Catalogue of Industries for Guiding Foreign Investment permit foreign companies to establish or invest in wholly foreign-owned companies or joint ventures that engage in wholesale or retail sales of pharmaceuticals in China. In relation to retail sales, the number and size of retail pharmacy outlets that a foreign investor may establish remain subject to certain restrictions. Pharmacy chains with more than 30 outlets and selling a variety of branded pharmaceutical products sourced from different suppliers are limited to less than 50.0% foreign ownership. However, under the Supplement Regulations for Administration Rules on Foreign Investment in Commercial Domains, a service provider from Hong Kong or Macau may provide up to 65% of the capital contributions to such pharmacy chains that it opens.

Good Supply Practices

GSP standards regulate pharmaceutical wholesale and retail distributors to ensure the quality of distribution in China. The current applicable GSP standards require pharmaceutical distributors to implement strict controls on the distribution of medicine products, including standards regarding staff qualifications, distribution premises, warehouses, inspection equipment and facilities, management and quality control. The GSP certificate is valid for five years.

Our subsidiaries, Shanghai Simcere and Jiangsu Simcere, obtained their respective most recent GSP certificates on November 21, 2008 and July 2, 2008. Both certificates are valid for five years and we do not believe it would be difficult for us to renew these certifications.

Product Liability and Protection of Consumers

Product liability claims may arise if the products sold have any harmful effect on the consumers. The injured party can claim for damages or compensation. The General Principles of the Civil Law of the PRC which was effective from January 1987 states that manufacturers and sellers of defective products causing property damage or injury shall incur civil liabilities.

The Product Quality Law of the PRC was enacted in 1993 and amended in 2000 to strengthen quality control of products and protect consumers rights. Under this law, manufacturers and distributors who produce and sell defective products may be subject to the confiscation of earnings from such sales, the revocation of business licenses and imposition of fines, and in severe circumstances, may be subject to criminal liability.

The Law of the PRC on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and enacted from January 1, 1994 to protect consumers rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. In extreme situations, pharmaceutical manufacturers and distributors may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

Price Controls

The retail prices of certain pharmaceuticals sold in China, primarily those included in the national and provincial Medical Insurance Catalogs and those pharmaceuticals whose production or trading are deemed to constitute monopolies, are subject to price controls in the form of fixed prices or price ceilings. Manufacturers and

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distributors cannot set the actual retail price for any given price-controlled product above the price ceiling or deviate from the fixed price imposed by the government. The prices of medicines that are not subject to price controls are determined freely at the discretion of the respective pharmaceutical companies, subject to notification to the provincial pricing authorities. Sales of pharmaceutical products by pharmaceutical manufacturers in China to overseas markets are not subject to any price control.

The retail prices of medicines that are subject to price controls are administered by the Price Control Office of the National Development and Reform Commission, or the NDRC, and provincial and regional price control authorities. The retail price, once set, also effectively determines the wholesale price of that medicine. From time to time, the NDRC publishes and updates a list of medicines that are subject to price controls. Fixed prices and price ceilings on medicines are determined based on profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, its production costs, the prices of substitute medicines and the extent of the manufacturer s compliance with the applicable GMP standards. The NDRC directly regulates the price of a portion of the medicines on the list, and delegates to provincial and regional price control authorities the authority to regulate the pricing of the rest of the medicines on the list. Provincial and regional price control authorities have discretion to authorize price adjustments based on the local conditions and the level of local economic development. Currently, approximately 1,500 pharmaceuticals, or approximately 10.0% of the pharmaceuticals available in China, are subject to price controls. Of those, the price controls for the retail prices of approximately 600 pharmaceuticals are administered by the NDRC and the rest are administered by provincial and regional price control authorities.

Only the manufacturer of a medicine may apply for an increase in the retail price of the medicine and it must either apply to the provincial price control authorities in the province where it is incorporated, if the medicine is provincially regulated, or to the NDRC, if the medicine is centrally regulated. For a provincially regulated medicine, in cases where provincial price control authorities approve an application, manufacturers must file the new approved price with the NDRC for record and thereafter the new approved price will become binding and enforceable across China.

Since May 1998, the PRC government has ordered reductions in the retail prices of various pharmaceuticals 24 times. The latest price reductions occurred in January, March, April and May of 2007 and affected a total of 466 different Chinese medicines and 614 different western pharmaceuticals.

The NDRC may grant premium pricing status to certain pharmaceuticals that are under price controls. The NDRC may set the retail prices of pharmaceuticals that have obtained premium pricing status at a level that is significantly more than comparable products. Two of our branded generic products, Zailin granules and Yingtaiqing capsules, have obtained premium pricing status from the NDRC.

Tendering System for Medicines Purchased by Healthcare Institutions

Hospitals owned and controlled by counties or higher level governments must implement collective tender processes for the purchase of medicines listed in the Medical Insurance Catalogs and medicines that are consumed in large volumes and commonly prescribed for clinical uses. A committee established by the hospitals consisting of recognized pharmaceutical experts must assess the bids submitted by the pharmaceutical manufacturers, taking into consideration, among other things, the quality and price of the medicine and the service and reputation of the manufacturers. For the same type of pharmaceutical, the committee usually selects from among two to three different brands. Any reduction in the pharmaceutical purchase price by these hospitals as a result of the competitive bidding process is intended to bring about a corresponding reduction in the retail price for the benefit of patients. At present, we understand that the extent of implementation of such tender purchase system varies among different regions in China. Recently, state-owned and state-controlled hospitals of certain provinces began to implement collective tender processes through online bidding. Such online bidding process is expected to increase the transparency and competitiveness of the tendering system. An increasing numbers of hospitals are expected to adopt such online bidding procedures.

Reimbursement Under the National Medical Insurance Program

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According to the PRC National Bureau of Statistics, as of December 31, 2008, 317.0 million people in China were enrolled in the National Medical Insurance Program. Most program participants are urban residents who are currently employed or retired. Participants of the National Medical Insurance Program and their employers are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the national Medical Insurance Catalog, which is divided into two tiers. Purchases of Tier A medicines are fully reimbursable, but certain Tier A medicines are only reimbursable if the medicine is used for a particular stated purpose in the Medical Insurance Catalogs. Purchasers of Tier B medicines are required to make a certain percentage of co-payments, with the remaining amount being reimbursable. The percentage of reimbursement for Tier B medicines varies in different regions in the PRC. Factors that affect the inclusion of medicines in the Medical Insurance Catalogs include whether the medicine is consumed in large volumes and commonly prescribed for clinical use in China and whether it is considered to be important in meeting the basic healthcare needs of the general public. The Ministry of Human Resources, together with other government authorities, has the power every two years to determine which medicines are included in the national medicine catalog, under which of the two tiers the included medicine falls, and whether an included medicine should be removed from the catalog. Provincial governments are required to include all Tier A medicines listed on the national Medical Insurance Catalog in their provincial Medical Insurance Catalogs. For Tier B medicines listed in the national Medical Insurance Catalog, provincial governments have the discretion to adjust upwards or downwards by no more than 15% from the number of Tier B medicines listed in the national Medical Insurance Catalog that is to be included in the provincial Medical Insurance Catalogs. The total amount of reimbursement for the cost of medicines, in addition to other medical expenses, for an individual participant under the National Medical Insurance Program in a calendar year is capped to the amounts in that participant s individual account under the program. The amount in a participant s account varies, depending on the amount of contributions from the participant and his or her employer. Generally, on average, participants under the National Medical Insurance Program who are from relatively wealthier parts of China and metropolitan centers have greater amounts in their individual accounts than those from less developed provinces.

PRC Patent Law

The PRC first allowed patents for the protection of proprietary rights, as set forth in the PRC Patent Law, in 1985. Pharmaceutical inventions were not patentable under the PRC Patent Law until 1993. Patents relating to pharmaceutical inventions are effective for 20 years from the initial date the patent application was filed. An amendment to the PRC Patent Law was promulgated on December 27, 2008, with the amendment becoming effective on October 1, 2009.

Patent Prosecution

The patent prosecution system in China is different from the U.S. system in a number of ways. The patent system in China, like most countries other than the United States, adopts the principle of first to file. This means that, where more than one person files a patent application for the same invention, a patent will be granted to the person who first filed the application. The United States uses a principle of first to invent to determine the granting of patents. In China, a patent must possess novelty, inventiveness and practical application. Under the existing PRC Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or abroad or has been publicly used or made known to the public by any other means in China, nor has any other person filed with the patent authority an application which describes an identical invention or utility model and is published after the filing date. Under the amended PRC Patent Law, novelty means that the invention or utility model is not an existing technology , and prior to the date of application, no entity or individual has filed an application with the patent authority describing the identical invention or utility model and is published after the filing date. The term existing technology refers to technology known to the general public both in China and abroad prior to the date of application. Patents issued in the PRC are not enforceable in Hong Kong, Taiwan or Macau, each of which has independent patent systems. Patents in the PRC are filed at the State Intellectual Property Office, or SIPO, in Beijing.

Patent Enforcement

When a dispute arises as a result of infringement of the patent holder s patent right, such dispute should be settled first through consultation by the respective parties. However, if such dispute cannot be settled through

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consultation, such patent holder or an interested party who believes the patent is being infringed may either file a civil legal suit or file an administrative complaint with a provincial or municipal office of the SIPO. A PRC court may issue a preliminary injunction upon the patent holder s or an interested party s request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as either the loss suffered by the patent holder arising from the infringement or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. In addition, under the amended PRC Patent Law, if damages can not be determined by either of the method described above, the court may at its discretion, by taking into account factors such as the type the patent or the nature and gravity of the infringement, determines a compensation in the sum of not less than RMB10,000 but not more than RMB1.0 million. As in other jurisdictions, with one notable exception, the patent holder in the PRC has the burden of proving that the patent is being infringed. However, if the holder of a manufacturing process patent alleges infringement of such patent, the alleged infringing party has the burden of proving that there has been no infringement.

Compulsory License

Under current PRC Patent Law, where a person possesses the means to utilize a patented technology, but such person cannot obtain a license from the patent holder on reasonable terms and in a reasonable period of time, such person is entitled to apply to the SIPO to authorize the grant of a compulsory license three years following the grant of the patented technology. However, under the amended PRC Patent Law, if a patent holder, after 3 years from the date when patent is granted and after 4 years from the date when a patent application is filed, fails to exploit or to fully exploit the patent without any good cause, the SIPO may, upon the application of an eligible entity or individual, grant such other party a compulsory license to exploit the patent. Furthermore, under the amended PRC Patent Law, if a patent holder s act of exercising the patent right is determined as a monopolizing act, a compulsory license may be granted in order to eliminate or reduce the adverse consequences of monopoly. A compulsory license may also be granted, under the current and the amended PRC Patent Law, where a national emergency or any extraordinary state of affairs occurs or where public interest so requires. For the pharmaceutical industry, the SIPO may, under the amended PRC Patent Law, grant a compulsory license for a patented medicine to a country or region subject to provisions of the relevant international treaty to which the PRC is a party in the interest of public health. We do not believe a compulsory license has yet been granted by the SIPO.

International Patent Treaties

The PRC is also a signatory to all major intellectual property conventions, including the Paris Convention for the Protection of Industrial Property, Madrid Agreement on the International Registration of Marks and Madrid Protocol, Patent Cooperation Treaty, Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPs.

Although patent rights are national rights, there is also a large degree of international co-operation under the Patent Cooperation Treaty, or the PCT, to which China is a signatory. Under the PCT, applicants in one country can seek patent protection for an invention simultaneously in a number of other member countries by filing a single international patent application. The fact that a patent application is pending is no guarantee that a patent will be granted, and even if granted, the scope of a patent may not be as broad as the subject of the initial application.

Trademarks

The PRC Trademark Law was promulgated in 1982 (later amended on October 27, 2001) and the PRC Trademark Implementing Regulations was promulgated on August 3, 2002. The PRC Trademark Office is responsible for the registration and administration of trademarks throughout the country. Like patents, the PRC has adopted a first-to-file principle with respect to trademarks.

PRC law provides that the following acts constitute infringement of the exclusive right to use a registered trademark:

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use of a trademark that is identical with or similar to a registered trademark in respect of the same or similar commodities without the authorization of the trademark registrant;

sale of commodities infringing upon the exclusive right to use the trademark;

counterfeiting or making, without authorization, representations of a registered trademark of another person, or sale of such representations of a registered trademark;

changing a registered trademark and selling products on which the changed registered trademark is used without the consent of the trademark registrant; and

otherwise infringing upon the exclusive right of another person to use a registered trademark.

In the PRC, a trademark owner who believes the trademark is being infringed has three options:

The trademark owner can provide his trademark registration certificate and other relevant evidence to the State or local Administration for Industry and Commerce, or AIC, which can, at its discretion, launch an investigation. The AIC may take such actions as: order the infringer to immediately cease the infringing behavior, seize and destroy any infringing products and representations of the trademark in question, close the facilities used to manufacture the infringing products or impose a fine. If the trademark owner is dissatisfied with the State AIC s decision, he may, within 15 days of receiving the AIC s decision, institute civil proceedings in court.

The trademark owner may institute civil proceedings directly in court. Civil redress for trademark infringement includes:

injunctions;

requiring the infringer to take steps to mitigate the damage (i.e. print notices in newspapers); and

damages (i.e. compensation for the economic loss and injury to reputation as a result of trademark infringement suffered by the trademark holder).

The amount of compensation is calculated according to either the gains acquired by the infringer from the infringement during the infringement, or the loss suffered by the trademark owner, including expenses incurred by the trademark holder to deter such infringement. If it is difficult to determine the gains acquired by the infringer from the infringement, or the loss suffered by the trademark owner, the court may elect to award compensation of not more than RMB500,000.

If the case is so serious as to constitute a crime, the trademark owner may lodge a complaint with the relevant public security organ and the infringer is subject to investigation for criminal responsibility in accordance with PRC law.

The PRC is a signatory to the Madrid Agreement and the Madrid Protocol. These agreements provide a mechanism whereby an international registration produces the same effects as an application for registration of the mark made in each of the countries designated by the applicant.

Foreign Exchange Regulation

Pursuant to the Foreign Currency Administration Rules promulgated in 1996 and as subsequently amended from time to time and various regulations issued by SAFE and other relevant PRC government authorities, the Renminbi is freely convertible only to the extent of current account items, such as trade-related receipts and payments, interest and dividends. Foreign currencies received under current account items can be either retained or sold to financial institutions engaged in the foreign exchange settlement or sales business without prior approval from SAFE by complying with relevant regulations. Capital account items, such as direct equity investments, loans,

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repatriation of investments and investments in stocks and bonds, require the prior approval from SAFE or its local branch for conversion of Renminbi into a foreign currency, such as U.S. dollars, and remittance of the foreign currency outside the PRC.

Payments for transactions that take place within the PRC must be made in Renminbi. Foreign currencies received in respect of capital account items can be retained or sold to financial institutions engaged in the foreign exchange settlement or sales business only with prior approval from SAFE. Foreign-invested enterprises may retain foreign exchange in accounts with designated foreign exchange banks subject to a cap set by SAFE or its local branch.

Pursuant to the SAFE s Notice on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Financing and Inbound Investment via Overseas Special Purpose Vehicles, or SAFE Circular No. 75, issued on October 21, 2005, (i) a PRC citizen residing in the PRC, or PRC resident, shall register with the local branch of SAFE before it establishes or controls an overseas special purpose vehicle, or SPV, for the purpose of overseas equity financing (including convertible debts financing); (ii) when a PRC resident contributes the assets of or its equity interests in a domestic enterprise into an SPV, or engages in overseas financing after contributing assets or equity interests into an SPV, such PRC resident shall register his or her interest in the SPV and the change thereof with the local branch of SAFE; and (iii) when the SPV undergoes a material event outside of China, such as a change in share capital or merger and acquisition, the PRC resident shall, within 30 days from the occurrence of such event, register such change with the local branch of SAFE. PRC residents who are shareholders of SPVs established before November 1, 2005 were required to register with the local SAFE branch before March 31, 2006.

Under SAFE Circular No. 75, failure to comply with the registration procedures set forth above may result in the penalties, including imposition of restrictions on a PRC subsidiary s foreign exchange activities and its ability to distribute dividends to the SPV.

Our beneficial owners who are PRC residents have registered with the local branch of SAFE as required under SAFE Circular No. 75.

Dividend Distribution Regulation

The principal laws and regulations governing dividends paid by our PRC operating subsidiaries include the Company Law of the People s Republic of China (1993), amended and effective as of January 1, 2006, Wholly Foreign Owned Enterprise Law (1986), as amended in 2000, and Wholly Foreign Owned Enterprise Law Implementation Rules (1990), as amended in 2001. Under these laws and regulations, each of our PRC subsidiaries, including WFOEs and domestic companies in China may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries, including WFOEs and domestic companies is required to set aside at least 10.0% of its after-tax profit based on PRC accounting standards each year to its general reserves or statutory capital reserve fund until the accumulative amount of such reserve reaches 50.0% of its respective registered capital. These reserves are not distributable as cash dividends.

C. Organizational Structure

The following diagram illustrates our corporate structure and the place of organization of each of our subsidiaries as of the date of this annual report on Form 20-F.

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We conduct substantially all of our operations through the following operating subsidiaries in China:

Simcere Pharmaceutical Co., Ltd., or Hainan Simcere, is our wholly owned subsidiary that engages in the manufacturing of pharmaceutical products. Hainan Simcere is currently authorized to manufacture 64 pharmaceutical products;

Nanjing Simcere Dongyuan Pharmaceutical Co., Ltd., or Nanjing Simcere, is our wholly owned subsidiary that engages in the manufacturing of pharmaceutical products. Nanjing Simcere is currently authorized to manufacture 87 pharmaceutical products;

Jiangsu Simcere Pharmaceutical Co., Ltd., or Jiangsu Simcere, and Shanghai Simcere Pharmaceutical Co., Ltd., or Shanghai Simcere, are both our wholly owned subsidiaries that engage in the marketing, sales and distribution of pharmaceutical products;

Jiangsu Simcere Pharmaceutical R&D Co., Ltd., or Simcere Research, is our wholly owned subsidiary that engages in the research and development of pharmaceutical products;

Sichuan Zigong Yirong Industrial Co., Ltd., or Sichuan Simcere, is our wholly owned subsidiary that owns the mining right to a smectite mine in Sichuan Province and engages in the extraction of smectite, a raw material used for the manufacturing of one of our pharmaceutical products;

Hainan Qitian Pharmaceutical Co., Ltd., or Qitian Simcere, is our wholly owned subsidiary that engages in the processing and refinement of smectite;

Shandong Simcere Medgenn Bio-Pharmaceutical Co., Ltd., or Shandong Simcere, formerly known as Yantai Medgenn Co., Ltd., is our wholly owned subsidiary that engages in the manufacturing of Endu

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in China. We completed the acquisition of 80.0% of the equity interest of Shandong Simcere in September 2006. We have since acquired the remaining 20.0% of the equity interest in Shandong Simcere, which is now our wholly owned subsidiary. In addition, Shandong Simcere owns a 40.0% equity interest in Medgenn (Hong Kong) Co., Ltd., or Hong Kong Medgenn that was acquired for no cash consideration. Hong Kong Medgenn has the exclusive right to engage in the development and sale of Endu in any jurisdiction outside of the PRC until February 10, 2015. Hong Kong Medgenn has not conducted any operations to date;

Jilin Boda Pharmaceutical Co., Ltd., or Jilin Boda, is our 51.0% owned subsidiary that engages in the manufacturing and sale of pharmaceutical products. We completed the acquisition of the 51.0% equity interest in Jilin Boda in October 2007;

Nanjing Tung Chit Pharmaceutical Company Limited, or Nanjing Tung Chit, is our 85.71% owned subsidiary that engages in the manufacturing and sale of pharmaceutical products. We completed the acquisition of the 85.71% equity interest in Nanjing Tung Chit in November 2007 through our purchase of 100% equity interest in Master Luck Corporation Limited; and

Wuhu Simcere Zhong Ren Pharmaceutical Co., Ltd. is our 70.0% owned subsidiary that engages in the manufacturing and sale of pharmaceutical products. We completed the acquisition of the 70.0% equity interest in Wuhu Simcere Zhong Ren in April 2008.

Jiangsu Yanshen Biological Technology Stock Co., Ltd., or Jiangsu Yanshen, is our 37.5% owned subsidiary that engages in the manufacturing and sale of pharmaceutical products. We completed the acquisition of the 37.5% equity interest in Jiangsu Yanshen in May 2009.

D. Property, Plant and Equipment

Our headquarters and our research and development facility are located in Nanjing, Jiangsu Province, on a parcel of land with an aggregate site area of approximately 193,100 square meters. The land use right will expire in 2056. We have six GMP-approved manufacturing facilities that are located in Nanjing in Jiangsu Province, Haikou in Hainan Province, Liaoyuan in Jilin Province, Yantai in Shandong Province and Wuhu in Anhui Province. Our facilities in Nanjing are approximately 36,677 square meters in total, occupying four parcels of land with an aggregate site area of approximately 309,788 square meters. The land use rights granted with respect of the lands will expire in 2048, 2054 and 2054 and 2056. Our facility in Haikou, Hainan Province is approximately 17,000 square meters and occupies a parcel of land with an aggregate site area of approximately 40,000 square meters. The land use right will expire in 2067. The facility in Yantai, Shandong Province is approximately 3,000 square meters and occupies a parcel of land with an aggregate site area of approximately 48,000 square meters. The land use right will expire in 2053. The facility in Liaoyuan, Jilin Province is approximately 33,410 square meters and occupies an aggregate site area of approximately 67,207 square meters. The land use rights will expire in 2028 and 2056, respectively. The facility in Wuhu, Anhui Province is approximately 2,118 square meters and occupies a parcel of land with an aggregate site area of approximately 20,000 square meters. The land use right will expire in 2052. In addition, we own the mineral exploration right relating to a smectite mine that can produce 300,000 ton in total of smectite, a raw material used for the manufacturing of our diarrhea medicine Biqi. We believe that our existing facilities, together with the facilities under construction, are adequate for our current requirements.

Item 5. Operating and Financial Review and Prospects

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements included elsewhere in this annual report on Form 20-F . This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under Item 3. Key Information D. Risk Factors or in other parts of this annual report on Form 20-F.

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A. Operating Results

Overview

We are a leading manufacturer and supplier of branded generic pharmaceuticals in the fast growing China market. We focus our strategy on the development of first-to-market generic and innovative pharmaceuticals. We currently manufacture and sell 45 principal pharmaceutical products and are the exclusive distributor of three additional pharmaceutical products that are marketed under our brand names. We market and sell our products directly or indirectly to approximately 1,700 pharmaceutical distributors who in turn sell these products to other distributors, hospitals and retail pharmacies throughout China.

We commenced operations in March 1995 and operated our business mainly as a distributor of pharmaceutical products. Since then, we have gradually built up our research and development and manufacturing capabilities and have become one of the leading pharmaceutical companies in China that develop, manufacture and sell branded generic pharmaceuticals. To date, we have introduced a series of branded products, including our first-to-market generic anti-stroke medication Bicun, as well as our innovative pharmaceutical Endu, the first recombinant human endostatin injection approved for sale in China. Revenues from our Bicun, Zailin, Endu and Yingtaiqing products have each exceeded RMB100.0 million ($14.7 million) in 2008, which we believe is evidence of wide market acceptance of these products in the China market.

In May 2006, we entered into a purchase agreement to acquire an 80.0% equity interest in Shandong Simcere, a PRC pharmaceutical company engaged in the research, development, manufacture and sale of an anti-cancer drug under the name Endu. Prior to the completion of the acquisition, we began to distribute Endu as Shandong Simcere s exclusive distributor in July 2006. The acquisition was completed in September 2006, after which we began to manufacture Endu. Through this acquisition, we have also acquired the patents and the rights to manufacture and sell Endu in China, as well as a GMP-certified manufacturing facility for the production of Endu. We have since acquired the remaining 20.0% equity interest in Shandong Simcere, which is now our wholly owned subsidiary. In October 2007, we completed the acquisition of a 51.0% equity interest in Jilin Boda, which manufactures the only other edaravone injection available in China in addition to our existing product Bicun at that time, and in November 2007, we completed the acquisition of an 85.71% equity interest in Nanjing Tung Chit, the manufacturer of nedaplatin injection, a chemotherapy pharmaceutical that is marketed under the brand name Jiebaishu. In April 2008, we acquired a 70.0% equity interest in Wuhu Simcere Zhong Ren, the manufacturer of sustained release implants for the treatment of cancer that is marketed under the brand name Sinofuan.

We have experienced significant growth in our business in recent years. Our total revenues increased from RMB950.6 million in 2006 to RMB1,368.7 million in 2007 and to RMB1,741.1 million ($255.2 million) in 2008, representing a CAGR of 35.3% from 2006 to 2008. Our net income increased from RMB172.3 million in 2006 to RMB301.3 million in 2007 and to RMB350.2 million ($51.3 million) in 2008, representing a CAGR of 42.6% from 2006 to 2008.

We believe that the most significant factors that affect our financial performance and results of operations are:

- the growth of the pharmaceutical market in China;
- our ability to successfully develop, acquire and launch first-to-market branded generic and innovative pharmaceuticals;
- the extent of inclusion of our pharmaceuticals in the Medical Insurance Catalogs;
- our ability to compete in the tender processes for purchase of medicines by state-owned and state-controlled Chinese hospitals; and
- product pricing and price controls.

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The Growth of the Pharmaceutical Market in China

With approximately one-fifth of the world s population and a fast-growing gross domestic product, China represents a significant potential market for the pharmaceutical industry. We believe the significant expected growth of the pharmaceutical market in China is due to factors such as robust economic growth and increased pharmaceutical expenditure, aging population and increased lifestyle-related diseases, government support of the pharmaceutical industry, the relatively low research and development and clinical trial costs in China as compared to developed countries, as well as the increased availability of funding for medical insurance and industry consolidation in China.

Our business and revenue growth primarily depend on the size of the pharmaceutical products in China. As a result, our revenue and profitability may be negatively affected by changes in national, regional or local economic conditions and consumer confidence in China. In particular, as we focus our expansion of retail stores in metropolitan markets, where living standards and consumer purchasing power are higher than rural areas, we are especially susceptible to changes in economic conditions, consumer confidence and customer preferences of the urban Chinese population. External factors beyond our control that affect consumer confidence include unemployment rates, levels of personal disposable income, national, regional or local economic conditions and acts of war or terrorism. Changes in economic conditions and consumer confidence could adversely affect consumer preferences, purchasing power and spending patterns. For example, the recent global economic and financial market crisis has caused, among other things, lower customer spending across China. As a result, sales of our premium priced high-end anti-cancer medication Endu, which is currently excluded from national medical insurance catalogue, have declined and may continue to decline as patients decrease their purchases as a result of worries about economic conditions or reduced incomes. In addition, the timing and nature of any recovery in the credit and financial markets remains uncertain, and there can be no assurance that market conditions will improve in the near future or that our results will not continue to be materially and adversely affected.

Our Ability to Successfully Develop, Acquire and Launch First-to-Market Generic and Innovative Pharmaceuticals

We believe that our proven ability to build a portfolio of first-to-market branded generic and innovative pharmaceuticals is crucial for our long-term growth and profitability, as first-to-market pharmaceuticals provide the advantage of rapid market penetration and higher profit margins. Compared to other generic pharmaceuticals, which can be sold by other pharmaceutical companies at a lower price, first-to-market generic pharmaceuticals, although not protected by intellectual property rights, are often granted a monitoring period, or have been granted a protection period under prior regulations, by the SFDA during which time the SFDA will not accept applications for new medicine certificates for pharmaceuticals with the same chemical structure, dosage form and indication. Innovative pharmaceuticals, which are protected by intellectual property rights, enjoy an even longer period of exclusivity as the validity period for an invention patent is 20 years. We believe that our ability to launch first-to-market generic and innovative pharmaceuticals, the exclusive marketing period in relation to such pharmaceuticals, coupled with our capabilities in marketing, branding and distribution, will continue to allow us to develop products that gain widespread recognition quickly and contribute to the rapid increase of our revenues and profitability.

The Extent of Inclusion of Our Pharmaceuticals in the Medical Insurance Catalogs

Eligible participants in the national basic medical insurance program in China, which consists of mostly urban residents, are entitled to reimbursement from the social medical insurance fund for up to the entire cost of medicines that are included in the national and provincial Medical Insurance Catalogs. See Item 4. Information of the Company B. Business Overview Regulation Reimbursement Under the National and Provincial Medical Insurance Programs. Factors that affect the inclusion of medicines in the Medical Insurance Catalogs include whether the medicine is consumed in large volumes and commonly prescribed for clinical use in China and whether it is considered to be important in meeting the basic healthcare needs of the general public. As of March 31, 2009, 24 of our 45 principal products that were manufactured and sold were included in the national Medical Insurance Catalog and 15 were included in the Medical Insurance Catalog of various provinces, municipalities and autonomous regions. The inclusion of a medicine in the Medical Insurance Catalogs can substantially improve the sales volume of the medicine due to the availability of third-party reimbursements. However, pharmaceuticals included in the Medical Insurance Catalogs are subject to price controls in the form of fixed retail prices or retail

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price ceilings, and are subject to periodical price adjustments by the relevant regulatory authorities. Such price controls, especially downward price adjustments, may negatively affect the unit price of our products. See Product Pricing and Price Controls. On balance, we believe that the benefit of the inclusion of our pharmaceuticals in the Medical Insurance Catalogs outweighs the cost of such inclusion.

There can be no assurance that our products currently included in the Medical Insurance Catalogs will continue to be included in the catalogs. The removal or exclusion of our products from the Medical Insurance Catalogs may adversely affect the sales of these products. The commercial success of our new and potential products is substantially dependent on whether and to what extent reimbursement is or will be available. Our failure to obtain inclusion of our new and potential products in the Medical Insurance Catalogs may adversely affect the future sales of those products. See Item 3. Key Information D. Risk Factors Risks Related to Our Company There is no assurance that our existing products will continue to be included or new products developed by us will be included in the Medical Insurance Catalogs.

Our Ability to Compete In the Tender Processes for Purchase of Medicines by State-Owned and State-Controlled Chinese Hospitals

A substantial portion of the products we sell to our distributor customers are sold to hospitals owned or controlled by counties or higher level government authorities in China. These hospitals must implement collective tender processes for the purchase of medicines listed in the Medical Insurance Catalogs and medicines that are consumed in large volumes and commonly prescribed for clinical uses. Factors considered by these hospitals in assessing bids include, among other things, the quality and price of the medicine and the service and reputation of the manufacturers. The collective tender process for pharmaceuticals with the same chemical composition must be conducted at least annually, and pharmaceuticals that have won in the collective tender processes previously must participate and win in the collective tender processes in the following period before new purchase orders can be issued. If we are unable to win purchase contracts through the collective tender processes in which we decide to participate, we will lose market share to our competitors, and our revenue and profitability will be adversely affected.

Product Pricing and Price Controls

Certain of our pharmaceutical products sold in China, primarily those included in the Medical Insurance Catalogs, are subject to price controls in the form of fixed prices or price ceilings. Controls over and adjustments to the retail price of a pharmaceutical may have a corresponding impact on the wholesale price of that pharmaceutical. From time to time, the PRC government publishes and updates a list of medicines that are subject to price controls, either at the national level or the provincial or regional level. Fixed prices and price ceilings on medicines are determined based on profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, its production costs, the prices of substitute medicines and the extent of the manufacturer s compliance with the applicable GMP standards. See Item 4. Information of the Company B. Business Overview Regulation Price Controls.

As of March 31, 2009, 24 of our 45 principal products that were manufactured and sold were included in the national Medical Insurance Catalog and were subject to price controls at the national level. In addition, 15 were included in the relevant provincial Medical Insurance Catalogs and were subject to price controls within the respective province, municipality or autonomous region. However, PRC government authorities impose no control over the prices at which pharmaceutical manufacturers sell their products to their distributors. Nevertheless, the prices at which pharmaceutical manufacturers such as us sell products to distributors are impacted by the relevant fixed retail price or retail price ceilings.

Since May 1998, the relevant PRC government authorities have ordered price reductions of various pharmaceuticals 24 times. The latest price reductions occurred in January, March, April and May of 2007 and affected a total of 466 different Chinese medicines and 614 different western pharmaceuticals. We expect the retail prices of additional pharmaceuticals to be adjusted periodically in the future. Since January 1, 2006, the retail price of Faneng, Nanyuan and Zaiqi were adjusted downward. Such retail price control, especially future downward price adjustments, may negatively affect our revenues and profitability. The following table sets forth the relevant information with respect to historical retail price adjustments of our products since January 1, 2006:

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Product	Brand	Dosage Form	Date of Adjustment	Maximum Retail Price Before Adjustment (RMB)	Maximum Retail Price After Adjustment (RMB)
Herbal Cough Medicine	Simcere Kechuanning	Liquids (6 10ml vials per box)	March 15, 2007	16.9	16.8
Amlodipine maleate	Ningliping	Tablets (10 5mg tablets per box)	January 26, 2007	45.0	38.8
Benazepril hydrochloride	Puliduo	Tablets (14 10mg tablets per box)	January 26, 2007	47.0	41.1
Alfacalcidol	Faneng	Capsules (20 0.25ug capsules)	January 26, 2007	52.0	38.6
	Faneng	Capsules (30 0.25ug capsules)	January 26, 2007	78.0	47.1
Ribavirin dispersible	Nanyuan	Dispersible tablets (24 0.1g packs)	August 28, 2006	18.2	8.1
Azithromycin	Zaiqi	Granules (6 0.1g packs)	October 10, 2005	24.6	12.5

Two of our branded generic products, Zailin granules and Yingtaiqing capsules, have obtained premium pricing status from the NDRC, which means the respective maximum retail prices of these products are fixed by the NDRC at a level that is generally substantially higher than those of comparable products. We believe that such premium pricing status has historically contributed to our sales of Zailin and Yingtaiqing by allowing us to set higher unit prices for these products as well as by ultimately increasing their sales volume as hospitals often assign higher points in assessing bids for medicines that have obtained premium pricing status, as such premium pricing status is deemed as recognition of high quality, strong efficacy and widespread market acceptance of the pharmaceutical.

The prices of medicines that are not subject to price controls are determined freely at the discretion of the respective pharmaceutical companies, subject to notification to the provincial pricing authorities. As we sell our products exclusively to pharmaceutical distributors in China, we price our pharmaceuticals that are not subject to price controls based on the prices of competing pharmaceuticals, if any, in the market and our gross margin. For instance, currently Endu is not subject to any price controls.

Acquisitions

On May 28, 2006, we entered into an agreement to acquire an 80.0% equity interest in Shandong Simcere, a PRC pharmaceutical company engaged in the research, development, manufacture and sale of an anti-cancer medication under the name Endu. Prior to the completion of the acquisition, we began to market and sell Endu in July 2006 through Jiangsu Simcere as the exclusive distributor for Shandong Simcere in China. Upon completion of the acquisition on September 30, 2006, we also began to manufacture Endu in China. Under the share purchase agreement, we agreed to pay Shandong Simcere s existing shareholders a total purchase price of RMB196.6 million, payable in cash, of which a total of RMB186.8 million has been paid as of December 31, 2006. According to the agreement, the remaining balance of RMB9.8 million will be paid upon completion of the trial period for certain quality control measures in relation to Endu, which are procedural in nature. In June 2007, we further acquired an additional 10.0% equity interest in Shandong Simcere for RMB27.1 million in cash. In January 2009, we acquired the remaining 10.0% equity interest in Shandong Simcere for RMB30.1 million ($4.4 million) payable in cash. We believe that our current levels of cash and cash flows from operations will be sufficient to meet our remaining payment obligation with respect to the acquisition.

In September 2007, we entered into a definitive agreement to acquire a 51.0% equity interest in Jilin Boda for a total of RMB123.1 million in cash. The acquisition was completed in October 2007. Jilin Boda manufactures the injectable stroke management medication, Yidasheng, the only other edaravone injection currently available in China

other than Bicun at that time. In November 2007, we acquired 100% equity interest in Master Luck

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Corporation Limited, which in turns holds an 85.71% equity interest in Nanjing Tung Chit, the manufacturer of nedaplatin injection, a chemotherapy pharmaceutical that is marketed under the brand name Jiebaishu. Total consideration for the acquisition was RMB32.9 million in cash. We believe Jiebaishu, as a leading nedaplatin product in China, further complements our current portfolio of anti-cancer pharmaceuticals that already include our innovative pharmaceutical Endu, as well as provide us with a manufacturing facility and production line for chemotherapy pharmaceuticals that is in compliance with GMP standards. In April 2008,we acquired a 70.0% equity interest in Wuhu Simcere Zhong Ren, the manufacturer of first-to-market 5-FU sustained release implants for the treatment of cancer under the brand name of Sinofuan, with a total consideration of RMB65.1 million ($9.5 million) in cash. The acquisition enhances our offerings in the anti-drug market and creates synergies with Endu, the anti-tumor drug.

In May 2009, we entered into an agreement to indirectly acquire approximately 35% of the equity interest of Shanghai Celgen for a total cash consideration of RMB140.0 million. Shanghai Celgen has strong expertise in research and production of therapeutic antibodies and possesses an antibody manufacturing facility in Shanghai, for which GMP certification is pending. Shanghai Celgen s major biogeneric drug candidate, an etanercept, has completed clinical trials and is currently awaiting approval from the SFDA. In addition, we are entitled to unwind the acquisition and the selling shareholders are required to return the amounts paid by us if the SFDA does not approve Shanghai Celgen s major biogeneric drug candidate within 24 months from the date of agreement. The agreement is subject to certain closing conditions.

In May 2009, we entered into an agreement to acquire a 37.5% equity interest in Jiangsu Yanshen, a China-based developer and manufacturer of vaccines, from existing shareholders for a total cash consideration of approximately RMB195.5 million. Jiangsu Yanshen s core products include an influenza vaccine and a human use rabies vaccine (vero cell). Upon the closing of the transaction, we are expected to be the largest shareholder in Jiangsu Yanshen. Jiangsu Yanshen has received a new medicine certificate from the SFDA for its freeze-dried human use rabies vaccine (vero cell) and has completed clinical trials of its purified hepatitis A inactivated vaccine (vero cell). SFDA approval for the purified hepatitis A inactivated vaccine (vero cell) and GMP certification for the associated new manufacturing facility are pending.

Revenues

We generate revenue mainly from the sales of our products. Our product revenues represent our revenues from the sales of our products, less value-added taxes, or VAT. Our total revenues also include other revenue, which primarily represent the refund of a portion of the VAT paid.

Our products include antibiotics, anti-stroke medications, anti-inflammatory drugs, anti-cancer medications and other medicines. We generate a substantial portion of our revenue from sales of Bicun, Zailin, Endu and Yingtaiqing, which in aggregate, accounted for 70.6%, 78.5% and 71.8% of our product revenues in 2006, 2007 and 2008, respectively.

The following table sets out a breakdown of our revenues for these major products, and each item expressed as a percentage of our product revenues, for the periods indicated:

	Year Ended December 31,					
	2006		2007		2008	
	(in thousands of RMB)	(% of product revenues)	(in thousands of RMB)	(% of product revenues)	(in thousands of RMB)	(% of product revenues)
Bicun	230,867	24.4	426,216	31.3	570,584	32.9
Zailin	266,790	28.1	287,333	21.0	290,215	16.7
Endu	34,726	3.7	216,193	15.9	239,439	13.8
Yingtaiqing	136,754	14.4	140,824	10.3	146,660	8.4

We sell our products exclusively to pharmaceutical distributors as we believe this is the most cost-effective way to reach a broad end-user base. We typically enter into written distribution agreements with our distributor customers for one-year terms that are generally renewed annually. Our sales are generally made on a purchase order basis, rather than under any long-term commitments. We compete for desired distributors with other pharmaceutical

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manufacturers. Any disruption of our distribution network, including failure to renew existing distribution agreements with desired distributors or establish relationships with important new distributors, could negatively affect our ability to effectively sell our products, which could materially and adversely affect our revenues and profitability. Furthermore, we have limited ability to manage the activities of our distributors as they are independent from us. Our distributors may potentially engage in actions that may violate the anti-corruption laws in China, engage in other illegal practices or exhibit and damaging behaviors with respect to their sales or marketing of our products, which could have a material adverse effect on our business, prospects and brand.

Our distributor customers are widely dispersed on both a geographic and revenues basis even though each distributor is limited to its respective designated distribution areas as specified in our distribution agreements. In 2006, 2007 and 2008, no single distributor contributed, on an individual basis, 10.0% or more of our total revenues, and sales to our five largest distributors accounted in aggregate for approximately 12.7%, 13.8% and 11.6%, respectively, of our product revenues.

We grant credit to a portion of our distributor customers in the normal course of business depending on the customers credit worthiness and the type of products we sell to them, although we require some customers to make payment prior to shipment. We grant different credit terms to different customers, depending on our assessment of their creditworthiness. We normally bill our distributor customers upon shipment for credit sales, with a typical 30 to 90 days credit term from the date of billing. Normally, collateral or other supporting securities are not required to support such credit sales.

We allow a portion of our distributor customers to make payment by bills receivable. Bills receivable primarily represents a short-term note receivable issued by a financial institution that entitles us to receive the full face amount from the financial institution at maturity, which generally ranges from 3 to 6 months from the date of issuance. Historically, we have not experienced any losses on bills receivable.

In the past, we have experienced limited amounts of uncollectible accounts receivable. In 2006, 2007 and 2008, the provision for bad debt expense amounted to RMB1.4 million, RMB1.2 million and RMB1.6 million ($0.2 million), respectively. Our allowance for doubtful accounts amounted to RMB7.7 million and RMB8.1 million ($1.2 million), as of December 31, 2007 and 2008, respectively.

Cost of Materials and Production and Operating Expenses

The following table sets forth our cost of materials and production and operating expenses as percentages of our total revenues for the period indicated:

	Year Ended December 31,		
	2006	**2007**	**2008**
		(in percentages)	
Cost of materials and production	20.0	17.6	18.4
Operating expenses			
Research and development expenses	3.6	4.9	4.9
Sales, marketing and distribution expenses	46.6	46.4	45.0
General and administrative expenses	10.3	11.8	11.2
Total operating expenses	60.5	63.1	61.1

Our cost of materials and production increased from 2006 to 2008 as a result of our increased sale of Bicun, Endu, Yidasheng and Sinofuan. However, our cost of materials and production declined as a percentage of our total revenues from 2006 to 2008 as the cost of materials and production of Bicun and Yidasheng as a percentage of their revenues is lower compared to those of our other major products as we manufacture the raw materials used for the manufacturing of Bicun and Yidasheng instead of purchasing such raw materials from third party suppliers. In addition, cost of materials and production as a percentage of revenues is lower for Endu and Sinofuan as compared to those of our generic pharmaceuticals. Our operating expenses as a percentage of our total revenues increased from 2006 to 2007. This increase was due primarily to the increase in our research and development expenses as a

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percentage of our total revenues, which was due primarily to the increase in research and development expenses associated with the Phase IV clinical trials for Endu and the continued expansion of our research and development activities. Our operating expenses as a percentage of our total revenues decreased from 2007 to 2008. The decrease was primarily due to the decrease in our sales, marketing and distribution expenses as a percentage of our total revenues as a result of improved economies of scale associated with the expansion of our operations. The increase from 2006 to 2008 in our general and administrative expenses associated with becoming a listed company in the United States in April 2007.

Cost of Materials and Production

Our cost of materials and production primarily consists of:

costs of the pharmaceuticals in which we are the exclusive distributors of;

costs of the necessary active ingredients and supporting ingredients of pharmaceuticals we manufacture and various types of packaging materials;

salaries and benefits for personnel directly involved in production activities;

overhead costs, including utility, maintenance of production equipment and other support expenses associated with the production of our products; and

depreciation of property, plant and equipment used for production purposes. Depreciation of property, plant and equipment attributable to production activities is capitalized as part of inventory, and expensed as cost of materials and production when products are sold.

As we produce our pharmaceuticals in China and we source or manufacture a significant portion of our raw materials in China, we currently have, and expect to continue to have in the foreseeable future, a relatively low cost base compared to the pharmaceutical manufacturers in more developed western countries. We expect the price of our raw materials to remain low as we are able to source raw materials within China at a low cost as the market for the supply of raw materials for pharmaceuticals is very competitive. As our business continues to expand and our economies of scale increase, we expect our bargaining power to increase, which we believe will also help in keeping our raw material costs low. Personnel costs in China have experienced a general upward trend, but as China possesses significant labor resources, we do not expect personnel costs as a percentage of total revenues to increase significantly in the near future. Overhead costs, on the other hand, have been increasing due to the increases in utility prices. However, we expect increased efficiencies in our manufacturing and production process to partially offset the increases in utility prices. We expect the depreciation of property, plant and equipment used for production purposes to increase as we continue to expand our production facilities, but we expect such increase to be in line with an increase in our production volume, and our depreciation cost as a percentage of our total revenues to remain relatively stable.

Research and Development Expenses

We concentrate our research and development efforts on the treatment of diseases with high incidence and/or mortality rates and/or for which there is a clear demand for more effective pharmacotherapy, such as cancer and cerebrovascular and infectious diseases. We believe such research and development strategy will lead to the development of products that have a high potential for commercialization and can maximize our growth rate and profit margin.

Our research and development expenses primarily consist of costs associated with the research and development of our product candidates. To develop product candidates, we use our in-house expertise as well as collaborate with leading universities and research institutions in China. Expenses associated with our in-house research and development activities include costs of engaging in market analysis to determine the commercial viability of potential pharmaceuticals, costs of employee compensation, costs of clinical pharmaceutical supplies, other supplies and materials, and intellectual property, travel and facilities costs. As to our collaboration

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arrangements with research institutions in China, we are generally responsible for the provision of funding and research assistance for the joint development of new pharmaceuticals. If the pharmaceuticals are successfully developed and new medicine certificates with respect to such pharmaceuticals are obtained, we will generally hold the rights to commercializing such products and in limited circumstances, will hold the rights to commercializing such products jointly with our research partners.

We are developing a number of new pharmaceuticals through our in-house expertise and through joint research and development efforts with universities and research institutions in China. As of March 31, 2009, we had over 12 product candidates in various stages of development. Product candidates that we believe have the highest potential for commercialization include palonosetron for injection and iguratimod tablets, all of which we are currently seeking SFDA approval. See C. Research and Development Product Candidates. We plan to commence the manufacturing, marketing and sales of these products as soon as we obtain the relevant SFDA approvals.

We entered into an agreement with Tsinghua University in February 2006 to establish a Joint Laboratory for Drug Discovery to engage in the research and development of innovative pharmaceuticals. The joint laboratory is operated under the direction of a management committee, which consists of six members, with Tsinghua University and us each appointing three members. The agreement has a term of three years. Under the agreement, we will provide funding of RMB1.7 million for the daily operations of the joint laboratory. As of December 31, 2008, we have provided an aggregate of RMB3.8 million that includes laboratory launch costs of RMB0.5 million, research and development expenses for 2006 and 2007 of RMB0.8 million and RMB1.3 million, respectively, and annual laboratory operation and maintenance expenses of RMB0.4 million for 2006, 2007 and 2008, respectively. We will further provide additional research funding of RMB2.2 million once appropriate research and development projects are identified and approved by the management committee. However, we are not obligated to provide research funding if no such appropriate project is identified or approved. As of December 31, 2008, a total of five research and development projects were approved and engaged by the joint laboratory. The obligations, rights and benefits of Tsinghua University and us as to each research and development project will be set out in a separate technological agreement to be entered into with respect to each project when we have determined that the results of such research and development project have commercialization potential.

We also entered into an agreement in January 2007 with Advenchen, a pharmaceutical research and development company in the United States as a research partner to engage in the research and development of, clinical studies for, and the commercialization of an anti-cancer pharmaceutical based on a chemical compound owned by Advenchen. Under the terms of the agreement, we agreed to provide research assistance and funding of up to RMB30.0 million of which RMB2.0 million has been provided in February 2007. We provided an additional RMB1.0 million upon receiving three successful batches of anti-cancer pharmaceutical samples in July 2007. Another RMB1.0 million was paid upon the launch of the pre-clinical study in July 2008. The remaining RMB26.0 million will be further provided if additional milestones as set forth under the agreement are achieved. In addition, if any government grants are received in relation to this research and development project, we agreed to provide an amount equal to 10.0% of such grant to Advenchen to be used in research activities that are related to the anti-cancer pharmaceutical covered under this agreement, such as the research and development of delivery mechanisms for the anti-cancer pharmaceutical. We also have a right to terminate the agreement if Advenchen cannot successfully obtain a valid invention patent in China for the chemical compound it owns at which point we will terminate any further research and development activities under the agreement, and Advenchen will refund half of the funding already provided to it under the agreement. Pursuant to the agreement, we will be entitled to all intellectual property rights, the right to commercialize and all interests in the anti-cancer pharmaceutical in China, and will share equally with Advenchen the intellectual property rights outside of China. In addition, we will pay Advenchen 3.5% of total revenues from the sales of the anti-cancer pharmaceutical in China, deducting the costs of packing, transportation, advertising and marketing, taxation, discounts and other relevant costs, until the expiration of its patent period, provided that the anti-cancer pharmaceutical is successfully developed and commercialized. We began in 2008 pre-clinical trials of the anti-cancer pharmaceutical under the agreement, including the pharmacodynamics researches on lung cancer, animal pharmacokinetics researches and safety evaluation researches. We estimate that such researches can be completed by the end of 2009 at which time we will apply with the SFDA for investigational new drug application.

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On December 12, 2008, we entered into an agreement to collaborate on the co-development and production of humanized RabMAb® antibody therapeutics for tumors with Epitomics, Inc., a provider of humanized rabbit monoclonal antibodies for therapeutic use. Under the agreement, we and Epitomics, Inc. will collaborate on pre-clinical and clinical trials, product manufacturing, and product distribution in the international markets. We will have the exclusive production and distribution rights in China. We agreed to pay a total funding of up to $5.0 million (RMB34.1 million) of which $1.0 million (RMB6.8 million) was paid to acquire the license rights of in-process R&D materials in January 2009. The remaining $4.0 million (RMB27.3 million) will be provided at various dates upon achievement of certain milestones as set forth under the agreement.

According to the agreement, we will hold the rights to commercialize the drug in China and Epitomics, Inc. will hold the rights to commercialize the drug outside China. In addition, if the anti-cancer pharmaceutical is successfully developed and commercialized, we will pay Epitomics, Inc. royalties on the net sales derived from the sales of this drug in China upon achieving certain agreed annual net sales level.

Prior to the drug entering Phase I clinical trial in the United States or Europe, we will enjoy 40% of the income derived from the sale, transfer, assignment, license and/or disposition of the drug outside China. After the drug entering Phase I clinical trail in the United States or Europe, we will enjoy 50% of the income derived from the sale, transfer, assignment, license and/or disposition of the drug outside China. However, this is subject to a condition that we are required to share 50% of the related development costs, as defined in the agreement, incurred outside China. Also, we will enjoy 50% of the profit arising from the sales of the drug outside China.

Our subsidiary Jilin Boda, which we acquired in October 2007, has entered into a licensing agreement on September 27, 2005 with Jilin Medical Research Institute for the rights to use, manufacture and sell Polaprezinc APIs and granules which are new medications for the treatment of gastric ulcer. Under the terms of the agreement, Jilin Medical Research Institute agreed to complete the application for the new medicine certificates and obtain the relevant production approvals, which we currently expected to be completed before June 30, 2010. As of March 31, 2009, Jilin Boda has paid an aggregate of RMB1.6 million of the total contractual amounts of RMB2.7 million. The remaining will be paid upon the approval of the new medicine certificates and when the production approvals are obtained. However, if such production approvals are not obtained, Jilin Boda will be entitled to the return of the already paid amount.

Our subsidiary Jilin Boda also entered into a licensing agreement for Qiyetongmai capsule, a new anti-stroke pharmaceutical, with Jilin Province TCM Engineering Research Center on June 18, 2007. Qiyetong capsule is a new drug used in the therapy of stroke. Under the terms of the agreement, Jilin Province TCM Engineering Research Center is to transfer the patents and the rights to use, manufacture and sell Qiyetongmai capsules and its API. Jilin Province TCM Engineering Research Center has also agreed under the agreement to complete the application for new medicine certificate and obtain the relevant production approvals before July 1, 2010. Amount to be paid under the agreement is RMB6.5 million. As of March 31, 2009, Jilin Boda has paid an aggregate of RMB1.8 million. If Jilin Province TCM Engineering Research Centre fails to perform its obligations under the agreement, Jilin Boda will be entitled to the return of the already paid amount.

In September 2007, our subsidiary Simcere Research entered into a technology development agreement with China Pharmaceutical University to develop Endu as a long acting pharmaceutical through the PEGylation process. The PEGylated Endu will reduce the number of times in which Endu is required to be administered to once every week or two weeks. Amount to be paid under the agreement is RMB2.9 million and as of March 31, 2009, Simcere Research has paid an aggregate of RMB0.8 million. In addition, Simcere Research has agreed under the agreement to transfer to China Pharmaceutical University 0.5% of the total revenue deriving from the sales of this pharmaceutical every year for three years upon successfully obtaining new medicine certificate. The PEGylated Endu is currently undergoing pre-clinical studies.

The successful development of pharmaceutical products can be affected by many factors. Product candidates that appear to be promising at their early phases of research and development may fail to be commercialized for various reasons, including the failure to obtain the necessary regulatory approvals. In addition, the research and development cycle for innovative pharmaceuticals for which we may obtain an approval certificate is long. The process of conducting basic research and various stages of tests and trials of a new innovative pharmaceutical before obtaining an

approval certificate and commercializing the product may require more than ten

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years. There is no assurance that our research and development projects will produce a commercially viable result. Even if such products can be successfully commercialized, they may not achieve the level of market acceptance that we expect, and our business and profitability could be materially and adversely affected. See Item 3. Key Information D. Risk Factors Our future research and development projects may not be successful. Furthermore, as the research and development cycle for innovative pharmaceuticals is long, our expenditures on current and future research and development projects are subject to many uncertainties. The cost of research and development projects may vary significantly over the life of a research and development project as a result of a variety of factors, including:

- the delay in research and development of certain projects preventing us to focus our resources on more promising product candidates;
- the intended use of a product candidate, which affects the length and timing of the research and development projects;
- the number of patients who participate in the clinical trials;
- the number of sites included in clinical trials;
- the length of time required to enroll clinical trial participants;
- the duration of patient treatment and follow-up during clinical trials;
- the costs of producing supplies of the product candidates needed for clinical trials; and
- the requirement and timing of SFDA approvals.

As a result of the uncertainties discussed above, we are unable to determine with any significant degree of certainty the duration and the completion costs of our research and development projects or when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates.

We expense research and development costs as and when incurred. These expenses include the costs of our internal research and development activities and the costs of research and development conducted by others on our behalf, such as through third-party collaboration arrangements discussed above. Upfront payments for research and development costs in connection with third party research and development collaboration arrangements prior to obtaining regulatory approval are recognized as research and development expenses as the research and development activities are performed. Refundable milestone payments made by us in advance to third parties under research and development arrangements are recorded as research and development expense when the specific milestone is achieved. Research and development costs incurred subsequent to obtaining regulatory approval are capitalized and amortized over the shorter of the remaining license period and the patent protection period for the product.

We have incurred research and development expenses of RMB34.3 million, RMB68.3 million and RMB86.1 million ($12.6 million) in 2006, 2007 and 2008, respectively, representing 3.6%, 4.9% and 4.9% of our total revenues, respectively.

We are committed to increase our research and development capabilities, and expect to incur higher research and development expenses as we plan to supplement our development of first-to-market generic pharmaceuticals in China with increasing efforts in the research and development of innovative pharmaceuticals. We have also received government grants for certain of our projects and such grants have been recorded as a reduction of our research and development expenses as disclosed in our consolidated financial statements.

Additionally, we have in the past sought, and may continue to seek, to acquire rights to development stage clinical products, technologies or suitable businesses that complement our expansion strategies and our existing products and products under development. To acquire these rights, we are required to utilize significant financial

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resources and incur increased in process research and development or intangibles amortization expense. Our research and development expenses also included depreciation of our new research facility after it was completed in January 2007.

We expect that our total research and development expenses will increase in absolute terms in the future.

Sales, Marketing and Distribution Expenses

Sales, marketing and distribution expenses consist primarily of salaries and related expenses for personnel engaged in sales, marketing, distribution and customer support functions and costs associated with advertising and other marketing activities including expenses of engaging professional promotion and marketing companies. We host in-person product presentations, conference and seminars for physicians, other healthcare professionals and research scholars to promote and generate awareness of our pharmaceuticals. For our OTC pharmaceuticals, we also carry out consumer advertising and educational campaigns. As the pharmaceutical market in China continues to grow, we plan to further develop and strengthen our sales, marketing and distribution network in order to increase the market recognition of our products and our Simcere brand name. In 2006, 2007 and 2008, sales, marketing and distribution expenses increased primarily as a result of the additional sales and marketing activities carried out by an increased number of sales personnel and our increased product offerings. In the near term, we expect our total sales, marketing and distribution expenses to increase as we continue to broaden our market reach and increase revenues by introducing new branded pharmaceuticals, such as our new innovative pharmaceutical Endu, and by enhancing and strengthening the brand names and marketing efforts of our existing portfolio of pharmaceuticals.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits for our administrative, finance and human resources personnel, depreciation of equipment and facilities of our administrative offices, amortization of rental facilities used for administrative purposes, bad debt expense, fees and expenses of legal, accounting and other professional services and other expenses associated with our administrative offices. We expect general and administrative expenses to increase as we recruit additional professionals and incur additional costs related to the growth of our business.

Share-Based Compensation Expenses

We adopted our 2006 share incentive plan on November 13, 2006, under which we issued to certain members of our directors, senior management and key employees on November 15, 2006 options to purchase 10.0 million ordinary shares at an exercise price of $4.20 per ordinary share. These options vest over a five-year period, with 20.0% of them vesting on November 14 of each year beginning in 2007. These options will expire on November 14, 2012. On March 29, 2007, we granted 1,045,000 options to our independent directors and certain employees with an exercise price equal to $6.75. These options vest over a five-year period, with 20.0% of them vesting on March 28 of each year beginning in 2008. On May 5, 2008, we granted 400,000 options to a senior executive officer with an exercise price equal to $6.755. These options vest over 4.85 year, with 20.0% of them vesting on March 8 of each year beginning in 2009. On December 24, 2008, we granted 100,000 options to a senior executive officer with an exercise price equal to $3.445. These options vest over 4.69 year, with 20.0% of them vesting on August 31 of each year beginning in 2009. All of the above options granted will also vest only if the option holder is still a director or an employee of our company at the time of the relevant vesting or unless otherwise approved by our compensation committee.

We account for share-based compensation expenses based on the fair value of the share options on the date of the grant and recognize the amount over the requisite service period.

We recognized share-based compensation in the amount of RMB3.4 million, RMB30.8 million and RMB25.5 million ($3.7 million) in 2006, 2007 and 2008, respectively. Share-based compensation expenses are allocated among each of research and development expenses, sales, marketing and distribution expenses and general and administrative expenses based on the nature of the work our employees were assigned to perform.

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On April 15, 2009, our compensation committee approved a share option exchange program that offered our eligible directors, employees and consultants the right to exchange vested and unvested outstanding share options to purchase our ordinary shares granted under the 2006 Share Incentive Plan for our restricted shares. The exchange ratio was determined based on the fair value of replacement restricted shares so that the fair value of the replacement restricted shares to be issued upon exchange would be approximately equivalent to the fair value of the share options surrendered by an individual. In addition, these replacement restricted shares are subject to substantially the same vesting schedule as the options that are validly tendered in the exchange offer. A total of 154 directors and employees accepted the offer, and tendered options to purchase an aggregate of 9,802,400 ordinary shares in exchange for an aggregate of 4,750,018 restricted shares, which were granted on May 7, 2009. The exchange of the share option awards for restricted shares was accounted for as a modification for awards which involves a cancellation of the original award and an issuance of a new award. We do not expect the effect of this award modification on share-based compensation expense over the remaining requisite service period to be significant.

Taxation and Incentives

On March 16, 2007, the National People s Congress passed the new CIT law which became effective as of January 1, 2008. The new CIT law provides that all enterprises in China, including foreign-invested companies, are subject to a uniform 25% corporate income tax rate and all tax reduction or exemption as well as incentives previously solely available to foreign-invested enterprises are cancelled. However, the new CIT law provides a five-year transition period from its effective date for those enterprises which were established before March 16, 2007 and were entitled to a preferential lower tax rate under the then effective tax laws or regulations as well as grandfathering tax holidays. The transitional tax rates are 18%, 20%, 22%, 24% and 25% for 2008, 2009, 2010, 2011 and 2012 onwards, respectively. In addition, entities previously entitled to a 2+3 tax holiday under the then effective tax laws and regulations shall continue to enjoy the tax holidays until they expire.

Further, entities that qualify as Advanced and New Technology Enterprises or ANTEs under the new CIT law are entitled to a preferential income tax rate of 15%. According to the Notice on Prepayment of Corporate Income Tax issued by the State Administration of Taxation, an ANTE recognized according to previous tax regulations prior to January 1, 2008 should be subject to a corporate income tax rate of 25% before it is re-identified as an ANTE under the new CIT law.

On April 14, 2008, the Management Measures of Identifying Advanced and New Technology Enterprises and its annex, Key Fields of New and High-Tech Supported by the State, were issued jointly by the Ministry of Science and Technology, State Administration of Tax and the Ministry of Finance that outlines the detailed procedures and measures to identify such ANTEs. In December 2008, Shandong Simcere and Boda were recognized by the Chinese government as ANTEs under the new CIT law and entitled to the preferential income tax rate of 15% from 2008 to 2010. Under the new CIT law, where the transitional preferential income tax policies and the preferential policies prescribed under the new CIT law and its implementation rules overlap, an enterprise shall choose to carry out the most preferential policy, but shall not enjoy multiple preferential policies. Shandong Simcere has chosen to enjoy the 2+3 tax holiday grandfathering treatment until its expiry in 2011.

Hainan Simcere and Nanjing Simcere were both converted from domestic companies into foreign-invested enterprises in March 2006. In addition, Shandong Simcere and Tung Chit are foreign-invested enterprises established in 1999 and 2001 respectively. Prior to January 1, 2008, Hainan Simcere, Shandong Simcere, Nanjing Simcere and Tung Chit, being production-oriented foreign investment enterprises, were each entitled to a 2+3 tax holiday. In addition, Hainan Simcere and Shandong Simcere, being located in one of the Special Economic Zones and Economic and Technological Development Zones, respectively, were entitled to a reduced income tax rate of 15%. Further, Shanghai Simcere was located in KangQiao Industrial Area and was granted a reduced income tax rate of 15% for 2007 by the local taxing authority.

Hainan Simcere, Nanjing Simcere and Tung Chit completed their two-year full income tax exemption in 2007. As a result of these preferential tax treatments and other local tax incentives, our effective income tax rates were 3.9%, 4.1% and 11.5% in 2006, 2007 and 2008, respectively.

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The new CIT law also provides that enterprises established outside of China whose de facto management bodies are located in China are considered resident enterprises and are generally subject to the uniform 25% corporate income tax rate as to their worldwide income. Under the implementation rules for the new CIT law issued by the PRC State Council, de facto management body is defined as a body that has material and overall management and control over the manufacturing and business operations, personnel and human resources, finances and treasury, and acquisition and disposition of properties and other assets of an enterprise. Although substantially all of our operational management is currently based in the PRC, it is unclear whether PRC tax authorities would require (or permit) our overseas registered entities to be treated as PRC resident enterprises.

Under the new CIT law and the implementation rules issued by the State Council, PRC income tax at the rate of 10% is applicable to dividends payable to investors that are non-resident enterprises , which do not have an establishment or place of business in the PRC, or which have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends have their sources within the PRC. Similarly, any gain realized on the transfer of ADSs or ordinary shares by such investors is also subject to 10% PRC income tax if such gain is regarded as income derived from sources within the PRC. If we are considered a PRC resident enterprise , it is unclear whether dividends we pay with respect to our ordinary shares or ADSs, or the gain you may realize from the transfer of our ordinary shares or ADSs, would be treated as income derived from sources within the PRC and be subject to PRC income tax. It is also unclear whether, if we are considered a PRC resident enterprise , holders of our ordinary shares or ADSs might be able to claim the benefit of income tax treaties entered into between China and other countries.

Critical Accounting Policies and the Use of Estimates

We prepare our consolidated financial statements in accordance with U.S. GAAP, which requires us to make judgments, estimates and assumptions that affect (i) the reported amounts of our assets and liabilities, (ii) the disclosure of our contingent assets and liabilities at the end of each reporting period and (iii) the reported amounts of revenues and expenses during each reporting period. We continually evaluate these estimates based on our own historical experience, knowledge and assessment of current business and other conditions, including the current economic environment, our expectations regarding the future based on available information and reasonable assumptions, which together form our basis for making judgments about matters that are not readily apparent from other sources. Since the use of estimates is an integral component of the financial reporting process, our actual results could differ from those estimates. We adjust such estimates and assumptions including our estimates of future operations. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Change in these estimates resulting from continuing changes in economic environment will be reflected in the consolidated financial statements in future periods. The current economic environment has increased the degree of uncertainty inherent in those estimates and assumptions. Some of our accounting policies also require a higher degree of judgment than others in their application.

When reading our financial statements, you should consider (i) our selection of critical accounting policies, (ii) the judgment and other uncertainties affecting the application of such policies, (iii) the sensitivity of reported results to changes in conditions and assumptions. We believe the following accounting policies involve the most significant judgment and estimates used in the preparation of our financial statements.

Allowance for Doubtful Accounts

We grant credit to a portion of our customers in the normal course of business depending on the customers credit worthiness and the type of products we sell to them, although we require some customers to make payment prior to shipment. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We determine the allowance by (1) analyzing specific customer accounts that have known or potential collection issues and (2) applying historical loss rates to the aging of the remaining accounts receivable balances. If circumstances related to specific customers change, our estimates of the recoverability of receivables could be further adjusted. In the event that we believe a trade receivable will become uncollectible, we record additional provision to increase the allowance for doubtful accounts. The accounting effect of this entry is a charge to income. We believe our allowance to doubtful accounts is sufficient to reflect the recoverability of our accounts receivable. If our business grows, we expect our accounts receivable balance to increase, as could our

allowance for doubtful accounts. If the financial condition of our customers deteriorates, our

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uncollectible accounts receivable could exceed our current or future allowances. See Revenues. Our accounts and bills receivables increased as compared to December 31, 2007 as a result of increased sales in the fourth quarter of 2008 and longer credit period granted to customers.

The following table presents the movement of allowance for doubtful accounts in 2006, 2007 and 2008:

	Year Ended December 31,			
	2006 RMB	2007 RMB	2008 RMB	2008 $
	(in thousands)			
Balance at the beginning of the year	5,556	6,834	7,709	1,130
Additions charged to bad debt expense	1,433	1,203	1,576	231
Additions related to acquisitions of subsidiaries		1,074		
Write-off of accounts receivable charged against the allowance	(155)	(1,402)	(1,216)	(178)
Balance at the end of the year	6,834	7,709	8,069	1,183

Inventories

We value our finished goods inventory at the lower of cost, which consists of the cost of direct labor and raw materials as well as allocation of variable and fixed production overheads, and market value. Variable production overheads are allocated to each unit of production based on the actual use of the production facilities and fixed production overheads are allocated to the cost of conversion based on the normal capacity of the production facilities. We determine normal capacity as being a reasonable level of production volume supported by sufficient customer demand without any abnormal equipment downtime due to shortages of materials and labor. Expenses relating to abnormal levels of idle or excess facilities, spoilage and similar costs are expensed as incurred. In 2006, 2007 and 2008, we did not incur any significant abnormal amounts of idle facility expenses or spoilage as our manufacturing facilities were operating at normal capacity. Our inventory as of December 31, 2008 increased as compared to December 31, 2007 because of the acquisition of the new product, Sinofuan, the launch of the new product, Anxin, and the build-up of inventories to meet the anticipated customer demand in 2009.

We write down the cost of inventory that we specifically identify and consider as obsolete. Finished goods inventory is considered obsolete when it has less than six months of remaining shelf life. Our raw materials and packaging materials are not subject to significant risk of obsolescence. We manage our inventory level based on our estimates of future demand within a specific time period, generally three months or less based on existing customer orders and, to a limited extent, forecasted customer orders. Given our manufacturing plan is primarily based on existing customer orders, we have recorded minimal inventory write-downs in the past. Our inventory write-downs for 2006, 2007 and 2008 were RMB2.1 million, RMB3.2 million and RMB3.0 million ($0.4 million), respectively.

Depreciation and Amortization

Our long-lived assets include property, plant and equipment, intangible assets such as customer relationships, developed technology and product trademarks, manufacturing licenses and goodwill.

Except for goodwill, we amortize our long-lived assets using the straight-line method over the estimated useful lives of the assets. We make estimates of the useful lives of property, plant and equipment (including the salvage values) and intangibles, in order to determine the amount of depreciation and amortization expense to be recorded during any reporting period. We estimate the useful lives at the time we acquire the assets based on our historical experience with similar assets as well as anticipated technological or other changes. If technological changes were to occur more rapidly than anticipated or in a different form than anticipated, we might shorten the useful lives assigned to these assets, which will result in the recognition of increased depreciation and amortization expense in future periods. There has been no change to the estimated useful lives and salvage values in 2006, 2007 and 2008.

Long-Lived Assets and Goodwill

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As of December 31, 2008, our intangible assets primarily consisted of developed technology and customer relationships that we acquired in connection with our acquisitions of a 90.0% equity interest in Shandong Simcere, a 51.0% equity interest in Jilin Boda, an 85.71% equity interest in Nanjing Tung Chit and a 70.0% equity interest in Wuhu Simcere Zhong Ren during 2006, 2007 and 2008. We allocate the cost of an acquired entity to the assets acquired and liabilities assumed based on their estimated fair value on the date of acquisition. This process is commonly referred to as the purchase price allocation. As part of the purchase price allocation, we are required to determine the fair value of any intangible assets acquired. The determination of the fair value of the intangible assets acquired involves certain judgments and estimates. These judgments can include, but are not limited to, the cash flows that an asset is expected to generate in the future.

The fair values of developed technology and customer relationships were determined by us with inputs from our independent appraisers.

The developed technology acquired in connection with our acquisitions represents the right to use, manufacture, market and sell patented and generic pharmaceuticals. These pharmaceuticals include the anti-cancer drug, Endu, the edaravone injection, Yidasheng, the nedaplatin injection, Jiebaishu, and 5-FU sustained release implant, Sinofuan. We estimated the fair value of the developed technology based on an income approach. Under this approach, fair value of an asset is determined based on the present value of projected future net cash flows associated with the use of the asset. The most significant estimates and assumptions inherent in the income approach when we valued the developed technology include: the growth rate of our revenue from sales; the earnings before interest and tax, or EBIT, margin derived from sales; the discount rate selected to measure the risks inherent in future cash flows; and our assessment of the product life cycle. We also considered competitive trends influencing the sales, including consideration of any technical, legal, regulatory, and economic barriers to entry. Any material change in any of the key assumptions would affect the fair value of the developed technology which would have an offsetting effect on the amount of goodwill recognized from the acquisitions. Future events, such as market acceptance, introduction of superior pharmaceuticals by our competitors, regulatory actions, safety concerns as to our pharmaceuticals, and challenges to and infringement of our intellectual property rights, could result in write-downs of the carrying value of the developed technology. We estimated the economic useful life of the developed technology by taking into consideration the remaining protection period of the underlying pharmaceuticals patent rights in China and the expected competitive trend in the PRC market. We adopted a straight-line method of amortization for the developed technology as the pattern in which its economic benefits are used up cannot be reliably determined. Material changes in any of our key assumptions would affect the fair value of our developed technology.

For customer relationships, the fair value was determined based on an excess earnings or income approach which takes into consideration the projected cash flows to be generated from these customers. Future cash flows are predominately based on the net income forecast of each project and the historical pricing, margins and expense levels of similar products, taking into consideration the relevant market size and growth factors, expected industry trends, individual pharmaceutical product life cycles, and the valid period of each product s underlying patent. The resulting cash flows are then discounted at a rate approximating our weighted average cost of capital.

We evaluate long-lived assets, including property, plant and equipment and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We assess recoverability by comparing the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, we recognize an impairment charge based on the amount by which the carrying amount of the asset exceeds the fair value of the asset. We estimate the fair value of the asset based on the best information available, including prices for similar assets and in the absence of an observable market price, the results of using a present value technique to estimate the fair value of the asset. For the periods presented, no impairment on our long-lived assets was recorded.

We evaluate goodwill at least annually for impairment, and more frequently if events and circumstances indicate that it might be impaired. We evaluate the recoverability of goodwill using a two-step impairment test approach at the reporting unit level at the end of each year. The first step of the impairment test involves comparing the fair value of our reporting unit with the reporting unit s carrying amount, including goodwill. Secondly, if the carrying amount of

the reporting unit exceeds its fair value, we then recognize an impairment loss for any excess of

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the carrying amount of the reporting unit s goodwill over the implied fair value of that goodwill. We determine the implied fair value of goodwill by allocating the fair value of the reporting unit in a manner similar to a purchase price allocation. The residual fair value after this allocation is the implied fair value of the reporting unit goodwill. As of December 31, 2007 and 2008, our goodwill balance was RMB161.5 million and RMB178.2 million ($26.1 million), respectively. Our goodwill balance as of December 31, 2007 related to our acquisition of Nanjing Simcere in 2003, our acquisition of 80.0% of Shandong Simcere in September 2006, the acquisition of an additional 10.0% interest in Shandong Simcere in June 2007, the 51.0% interest in Jilin Boda and the 100% interest in Master Luck. The increase in our goodwill balance in 2008 was primarily due to the acquisition of a 70.0% interest in Wuhu Simcere Zhong Ren in April 2008. The fair value of this reporting unit is determined using our market capitalization based on the quoted market price of our ordinary shares for the purpose of testing goodwill for impairment. There have been no impairment charges recognized for goodwill in 2006, 2007 and 2008.

Share-based Compensation

We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), or SFAS No. 123R, on January 1, 2006. Under SFAS No. 123R, we are required to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award and recognize the cost as an expense in our consolidated statements of income over the period during which an employee is required to provide service in exchange for the award.

We determined the fair value of options using the Black-Scholes option pricing model. Under this option pricing model, certain assumptions, including the risk-free interest rate, the expected term of the options, the expected dividends on the underlying ordinary shares, and the expected volatility of the price of the underlying share for the expected term of the option, are required in order to determine the fair value of the options. Additionally, our share price on the date of the option grant influences the fair value of the option. Notwithstanding that the exercise price of options approximates the estimated share price of our ordinary shares on the grant date, a higher share price would result in a higher option value.

For the purpose of determining the estimated fair value of our share options granted in 2006 and 2007, we believe expected volatility and estimated share price of our ordinary shares are the most sensitive assumptions since we were a privately held company at the time we granted our options. Changes in the volatility assumption and the estimated share price of our ordinary shares could significantly impact the estimated fair values of the options calculated by the Black-Scholes option pricing model. Expected volatility is estimated based upon the latest five-year average volatility of six guideline companies listed in the United States with similar business as ours, all of which had been trading for at least five years. Guideline companies were used because we did not have a trading history at the time the options were issued and prior to having sufficient share price history to calculate our own historical volatility, we believe that the average volatility of the guideline companies is a reasonable benchmark to use in estimating the expected volatility of our ordinary shares. For options granted in 2008, we used the historical volatility of our shares to estimate the expected volatility.

In determining the value of our ordinary shares for purposes of recording share-based compensation for the options granted on November 15, 2006, we have considered the guidance prescribed by the AICPA Audit and Accounting Practice Aid Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid. Specifically, paragraph 16 of the Practice Aid sets forth the preferred types of valuation that should be used. We have followed the level A recommendation, the most preferred method of valuation recommended by the Practice Aid, and established the fair value of our ordinary shares at the date of grant using a contemporaneous valuation by an independent valuation firm, American Appraisal China Limited, or American Appraisal, as of November 15, 2006. American Appraisal used a weighted average of equity value derived by using a combination of the income approach, or the discounted cash flow method, and the market approach, or the guideline company method. American Appraisal applied an equal weight for both the market approach and the income approach to arrive at the fair value for our ordinary shares. There was no significant difference between our enterprise value, or EV, derived using the income approach and our EV derived using the market approach.

For the market approach, American Appraisal considered the market profile and performance of the six guideline companies and used such information to derive market multiples. American Appraisal then calculated the following

three multiples for the guideline companies: EV to sales multiple, EV to earnings before interest, tax,

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depreciation and amortization, or EBITDA, multiple and EV to earnings before interest and tax, or EBIT, multiple. Due to the different growth rates, profit margins and risk levels between us and the guideline companies, price multiple adjustments were made. American Appraisal used the 2007 adjusted median price multiples of the guideline companies in the valuation of our ordinary shares.

For the income approach, American Appraisal utilized discounted cash flow, or DCF, analysis based on our projected cash flows from 2006 through 2011. American Appraisal used a weighted average cost of capital, or WACC, of 15.0%, based on the WACC of the guideline companies.

American Appraisal also applied a discount for lack of marketability of 11.0% to reflect the fact that there was no ready market for shares in a closely held company like us. When determining the discount for lack of marketability, the Black-Scholes option pricing model was used. Under this option pricing method, the cost of the put option, which can hedge the price change before the privately held shares can be sold, was considered as a basis to determine the discount for lack of marketability. This option pricing method was used because it takes into account certain company-specific factors, including our size and the volatility of the share price of the guideline companies engaged in the same industry. Volatility of 40.0% was determined by using the mean of volatility of the guideline companies used in the market approach.

The above assumptions used by American Appraisal in deriving the fair values were consistent with our business plan and major milestones achieved by us. American Appraisal also applied other general assumptions, including the following:

- no material changes in the existing political, legal, fiscal and economic conditions and pharmaceutical industry in China;
- no major changes in tax law in China or the tax rates applicable to our subsidiaries and consolidated affiliated entities in China;
- exchange rates between the Renminbi and U.S. dollar will not differ materially from current rates;
- our future growth will not be constrained by the lack of funding;
- our continuing ability to retain competent management and key personnel to support our ongoing operations; and
- industry trends and market conditions for the pharmaceutical and related industries will not deviate significantly from economic forecasts.

With respect to the options granted on March 29, 2007, our board of directors determined that the midpoint of the estimated price range for our initial public offering of $6.75 was a reasonable measure of the fair value of our ordinary shares.

For the options granted on November 15, 2006, we used an expected volatility of 40.0%, estimated share price of our ordinary shares of $4.16, expected term of the options of 5.5 years, expected dividend yield of 0.0% and a risk-free interest rate of 5.11%, resulting in an estimated fair value per option of $1.88. For the options granted on March 29, 2007, the same assumptions are used except that the estimated share price of our ordinary shares used was $6.75, resulting in an estimated fair value per option of $3.05.

For the options granted on May 5, 2008, we used the closing price of our ordinary shares of $6.755, an expected volatility of 58.8%, expected term of the options of 5.35 years, expected dividend yield of 0.0% and a risk-free interest rate of 3.69%, resulting in an estimated fair value per option of $3.73.

For the options granted on December 24, 2008, we used the closing price of our ordinary shares of $3.445, an expected volatility of 74.4%, expected term of the options of 5.19 years, expected dividend yield of 0.0% and a risk-free interest rate of 1.54%, resulting in an estimated fair value per option of $2.13.

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Income tax uncertainties and realization of deferred tax assets

Our income tax provision, related deferred tax assets and deferred tax liabilities are recognized and measured based on actual and expected future income, PRC statutory income tax rates, PRC tax regulations and tax planning strategies. Significant judgment is required in interpreting tax regulations in the PRC, evaluating uncertain tax positions, and assessing the likelihood of realizing deferred tax assets. Actual results could differ materially from those judgments, and changes in judgments could materially affect our consolidated financial statements.

At December 31, 2007 and 2008, we had total gross deferred tax assets of RMB36.1 million and RMB35.6 million ($5.2 million), respectively. We record a valuation allowance to reduce our deferred tax assets if, based on the weight of available evidence, we believe expected future taxable income is not likely to support the use of a deduction or credit in that jurisdiction. We evaluate the level of our valuation allowances quarterly, and more frequently if actual operating results differ significantly from forecasted results. At December 31, 2007 and 2008, our deferred tax asset valuation allowance was RMB26.1 million and RMB24.5 million ($3.6 million), respectively. Our total income tax expense was increased/(decreased) by RMB4.2 million, RMB15.6 million and (RMB1.6 million) (($0.2 million)) in 2006, 2007, and 2008, respectively, for changes in estimates regarding the realization of our deferred tax assets.

The change in valuation allowance for 2008 consisted primarily of an increase of RMB9.6 million ($1.4 million) mainly for Jiangsu Simcere s additional tax losses and a decrease of RMB11.1 million ($1.6 million) for release of Simcere Research s 2007 valuation allowance, of which RMB10.1 million ($1.5 million) utilized in 2008, as it moved from a cumulative loss position to a cumulative profit position. As of December 31, 2008, our management reassessed the valuation allowance of Simcere Research and concluded that it was more likely than not that sufficient future taxable income would be generated to realize its deferred tax assets.

On January 1, 2007, we adopted the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes or FIN 48. Upon adoption of FIN 48, we reclassified RMB14.2 million of unrecognized tax benefits for which a cash tax payment is not expected within the next twelve months to long-term liabilities in 2007. Our adoption of FIN 48 did not result in a cumulative effect adjustment to the opening balance of our retained earnings.

Under FIN 48, we determine whether it is more likely than not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based solely on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, it is presumed that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. In addition, a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon settlement. The tax positions are regularly reevaluated based on the results of the examination of income tax filings, statute of limitations expirations and changes in tax law that would either increase or decrease the technical merits of a position relative to the more likely than not recognition threshold.

In the normal course of business, we are regularly audited by the PRC tax authorities. The settlement of any particular issue with the applicable taxing authority could have a material impact on our consolidated financial statements.

Results of Operations

The following table sets forth a summary of our consolidated statements of income for the periods indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any other future period.

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	Year Ended December 31,					
	2006		2007		2008	
	RMB	% of Total Revenues	RMB	% of Total Revenues	RMB	% of Total Revenues
	(in thousands, except percentages)					
Product revenues	947,797	99.7	1,363,014	99.6	1,736,832	99.8
Other revenue (1)	2,809	0.3	5,734	0.4	4,311	0.2
Total revenues	950,606	100.0	1,368,748	100.0	1,741,143	100.0
Cost of materials and production	(190,560)	(20.0)	(241,081)	(17.6)	(320,882)	(18.4)
Gross profit	760,046	80.0	1,127,667	82.4	1,420,261	81.6
Operating expenses:						
Research and development expenses	(34,289)	(3.6)	(68,295)	(4.9)	(86,089)	(4.9)
Sales, marketing and distribution expenses	(442,757)	(46.6)	(634,449)	(46.4)	(782,960)	(45.0)
General and administrative expenses	(98,249)	(10.3)	(161,061)	(11.8)	(194,233)	(11.2)
Total operating expenses	575,295	(60.5)	(863,805)	(63.1)	(1,063,282)	(61.1)
Income from operations	184,751	19.5	263,862	19.3	356,979	20.5
Interest income	2,827	0.3	24,361	1.8	34,302	2.0
Interest expense	(10,705)	(1.2)	(6,346)	(0.5)	(4,693)	