Simcere Pharmaceutical Group Form 20-F June 24, 2008

## 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, 2007

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 No. 699-18 Xuan Wu Avenue, Xuan Wu District, Nanjing Jiangsu Province 210042 People s Republic of China Tel: (86) 25 8556 6666 x 8818

Fax: (86) 25 8547 7666 E-mail: zhaozhigang@simcere.com

(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. 125,006,200 ordinary shares, par value \$0.01 per share, as of December 31, 2007

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 b

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 b

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 b 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 o

Non-accelerated filer b

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

U.S. GAAP b

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 b

(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, 2005, 2006 and 2007.

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.

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#### **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 Earnings data and Selected Balance Sheet Data for, and as of the end of, each of the years in the five-year period ended December 31, 2007, are derived from our consolidated financial statements. Our consolidated financial statements as of December 31, 2006 and 2007 and for each of the years in the three-year period ended December 31, 2007, which have been audited by an independent registered public accounting firm, and the report thereon, are 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 periods.

	Year Ended December 31,							
	2003	2004	2005	2006	2007	2007		
	RMB	RMB	RMB	RMB	RMB	\$		
	(in thousands, except share, per share and per ADS data)							
Selected								
Consolidated								
Statement of								
Earnings Data								
Total revenues <sup>(1)</sup>	465,818	564,198	737,014	950,606	1,368,748	187,638		
Gross profit	321,756	410,403	565,940	760,046	1,127,667	154,589		
Research and								
development								
expenses	(11,716)	(19,907)	(16,288)	(34,289)	(68,295)	(9,362)		
Sales, marketing	(11,710)	(12,207)	(10,200)	(8 1,207)	(00,2/0)	(>,===)		
and distribution								
expenses	(192,751)	(230,865)	(312,426)	(442,757)	(634,449)	(86,975)		
General and				, , ,		, , ,		
administrative								
expenses	(84,840)	(77,593)	(87,139)	(98,249)	(161,061)	(22,080)		
Income from								
operations	32,449	82,038	150,087	184,751	263,862	36,172		
Foreign currency								
exchange gains					24,670	3,382		
Other Income <sup>(1)</sup>					20,526	2,814		
Net income <sup>(2) (3)</sup>	24,390	46,245	102,745	172,258	301,261	41,300		
Earnings per share								
basic	0.35	0.67	1.49	1.86	2.56	0.35		
Earnings per share	0.55	0.07	1.17	1.00	2.50	0.55		
diluted	0.35	0.67	1.49	1.86	2.48	0.34		

Earnings per ADS						
basic	0.70	1.34	2.98	3.72	5.13	0.70
Earnings per ADS	0.70	1.04	2.00	2.72	4.05	0.60
diluted	0.70	1.34	2.98	3.72	4.95	0.68
Basic weighted average number of shares Diluted weighted average number	69,000,000	69,000,000	69,000,000	92,695,890	117,534,566	117,534,566
of shares	69,000,000	69,000,000	69,000,000	92,695,890	121,667,507	121,667,507

(1) Total revenues include product revenues and other revenue. In 2007, in the Form 6-K furnished with the SEC on August 7, 2007 for the quarter ended June 30, 2007, an incentive payment of RMB20.5 million (\$2.8 million) we received from our depositary in connection with the establishment of the ADR program following our initial public offering was erroneously classified as part of other revenue. Such incentive payment is reclassified as other income other than income from operations.

(2) In 2007, the incentive payment received from our depositary in connection with

the establishment of the ADR program following our initial public offering had the effect of increasing our net income by RMB20.5 million (\$2.8 million) or RMB0.17 (\$0.02) per share on a basic basis and a diluted basis or RMB0.35 (\$0.05) per ADS on a basic basis and RMB0.34 (\$0.05) per ADS on a diluted basis.

(3) In 2007, four of our operating subsidiaries were eligible for certain exemptions from income tax, three of which expired at the end of 2007. The effect of the income tax exemptions increased our net income for 2006 and 2007 by RMB38.8 million (RMB0.42 per share) and RMB62.9 million (\$8.6 million) (RMB0.54 (\$0.07) per share), respectively. Prior to 2006, there were no tax exemptions in place.

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		Year Ended December 31,				
		2003	2004	2005	2006	2007
				(in percentag	ges)	
Other Consolidated Fin	ancial Data					
Gross margin		69.1	72.7	76.8	80.0	82.4
Operating margin		7.0	14.5	20.4	19.5	19.3
Net margin		5.2	8.2	13.9	18.2	22.0
			As of December 31,			
	2003	2004	2005	2006	2007	2007
	RMB	RMB	RMB	RMB	RMB	\$
			(in the	ousands)		
Selected						
Consolidated						
<b>Balance Sheet Data</b>						
Cash and cash						
equivalents	61,193	102,672	90,060	106,027	497,352	68,181
Short-term						
investments					470,000	64,431
Accounts receivable,						
net of allowance for						
doubtful accounts	95,884	67,459	83,393	61,723	167,786	23,001
Inventories	32,031	27,878	40,293	39,483	65,241	8,944
Amounts due from						
related parties	79,576	39,890	85,575	434	7,503	1,029
Total current assets	334,609	322,446	391,461	411,429	1,557,153	213,467
Property, plant and						
equipment, less						
accumulated	102 172	110 550	105 265	267.054	274.050	51 270
depreciation	123,173	119,558	125,365	267,054	374,058	51,279
Intangible assets, net Goodwill	20,310	18,020	15,731	163,148	251,221	34,439
	13,814	13,814	13,814	100,634	161,496	22,139
Total assets Short-term bank loans	519,019	581,041	621,227	1,034,547	2,472,208	338,910
	246 220	293,000	171 000	222 000	29,000	2 076
and borrowings Amounts due to	246,330	293,000	171,000	333,000	29,000	3,976
	15,045	12,908	78,153	1,352		
related parties	13,043	12,906	76,133	1,332		
Total current liabilities	385 882	156 717	121 195	568 172	3/12/627	46,971
Total shareholders	385,882	456,747	421,185	568,173	342,637	40,971
equity	108,437	119,990	192,537	442,740	1,983,816	271,957
Exchange Rate Informs		117,770	172,331	774,770	1,705,010	211,931

### **Exchange Rate Information**

This annual report on Form 20-F contains translations of certain RMB amounts into U.S. dollar amounts at specified rates. All translations from RMB to U.S. dollars were 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. Unless otherwise stated, the translations of RMB into U.S. dollars have been made at the noon buying rate in effect on Monday, December 31, 2007, which was RMB7.2946 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 20, 2008, the noon buying rate was RMB6.8796 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. The source of these rates is the Federal Reserve Bank of New York.

	Noon Buying Rate						
	Period						
Period	End	Average <sup>(1)</sup>	High	Low			
	(RMB per \$1.00)						
2003	8.2767	8.2772	8.2765	8.2800			
2004	8.2765	8.2768	8.2764	8.2774			
2005	8.0702	8.1826	8.0702	8.2765			
2006	7.8041	7.9579	7.8041	8.0702			
2007	7.2946	7.5806	7.2946	7.8127			
December	7.2946	7.3682	7.2946	7.4120			
2008							
January	7.1818	7.2405	7.1818	7.2946			
February	7.1115	7.1644	7.1100	7.1973			
March	7.0120	7.0722	7.0105	7.1110			
April	6.9870	6.9997	6.9840	7.0185			
May	6.9400	6.9725	6.9377	7.0000			
June (through June 20)	6.8796	6.9129	6.8770	6.9633			

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

B. Capitalization and Indebtedness

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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 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;

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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 research partners—employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our information to competitors. 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 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 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

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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 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, 2008, our product Zaichang was under a monitoring period which is to expire on March 13, 2013. In addition, the monitoring period for Bicun has expired on December 30, 2007. 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

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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 research institutions and universities in China 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.

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 research institutions and universities in China. 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 medicines 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 affect 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

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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 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 which 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:

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 1,500 pharmaceutical distributors in China. In 2005, 2006 and 2007, 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 10.9%, 12.7% and 13.8% 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 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.

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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 and 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 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 addition, government-sponsored anti-corruption campaigns from time to time could have a chilling effect on our marketing efforts to new hospital customers. Our sales representatives may rely on hospital visits to better educate physicians as to our products and to promote our brand awareness. Recently, there were occurrences in which certain hospitals denied access to sales representatives from pharmaceutical companies because the hospitals wanted to avoid the perception of corruption. If this attitude becomes widespread among our potential customers, our ability to promote our products may be adversely affected.