Simcere Pharmaceutical Group
Form 20-F
April 26, 2013
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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
x	**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** **For the fiscal year ended December 31, 2012**
	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**

Date of event requiring this shell company report . . . . . .

For the transition period from to

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)

Yushan Wan

Acting 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

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E-mail: wanyushan@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 class	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)

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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.

101,410,422 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.

o Yes x No

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.

o Yes x No

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.

x Yes o No

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).

x Yes o No

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 x	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company 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 x	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.

o Item 17 o Item 18

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).

o Yes x No

(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.

o Yes o No

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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, 2010, 2011 and 2012.

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 Comprehensive Income Data (other than ADS data), Other Consolidated Financial 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, 2012, are derived from our consolidated financial statements and related notes thereto. Our consolidated financial statements as of December 31, 2011 and 2012 and for each of the years in the three-year period ended December 31, 2012, 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.

	Year Ended December 31,					
	2008 RMB	2009 RMB	2010 RMB	2011 RMB	2012 RMB	2012 $
	(in thousands, except share and ADS data)					
Selected Consolidated Statement of Comprehensive Income Data						
Revenue	1,741,143	1,857,071	2,141,098	2,040,547	2,082,966	334,339
Gross profit	1,420,261	1,536,126	1,799,311	1,712,388	1,721,895	276,383
Operating expenses (other than impairment charges)	(1,063,282)	(1,357,518)	(1,581,393)	(1,618,840)	(1,625,526)	(260,915)

Impairment charges		(76,398)			(97,247)	(15,609)
Gain arising from loss of control of a subsidiary (1)					24,789	3,979
Other operating income(2)				50,000	15,650	2,512
Income from operations	356,979	102,210	217,918	143,548	39,561	6,350
Foreign currency exchange gains (losses), net	39,879	382	5,511	7,732	(923)	(148)
Other income(3)	1,104	2,971	2,286	15,036	11,429	1,834
Equity in losses of equity method affiliated companies		(56,532)	(14,716)	(12,192)	(4,859)	(780)
Net income attributable to Simcere Pharmaceutical Group(4)	350,151	26,428	172,411	178,389	56,957	9,142
Earnings per share basic	2.80	0.23	1.59	1.63	0.53	0.09
Earnings per share diluted	2.80	0.23	1.55	1.61	0.53	0.09
Earnings per ADS basic	5.61	0.46	3.18	3.25	1.06	0.17
Earnings per ADS diluted	5.60	0.45	3.10	3.23	1.06	0.17
Basic weighted average number of shares	124,921,934	115,099,258	108,321,562	109,738,705	106,996,531	106,996,531
Diluted weighted average number of shares	125,005,803	116,604,919	111,357,796	110,525,257	107,370,830	107,370,830

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(1) In 2012, the RMB24.8 million ($4.0 million) of gain arose from the disposal of the controlling interest in one of our subsidiaries as part of the establishment of our equity joint venture with Merck.

(2) In 2009, we acquired 100% equity interest in China Vax, which is a Cayman Islands investment holding company and holds a 15% equity interest in Jiangsu Quanyi. In March 2012, we reached a settlement agreement with the selling shareholders and former directors of China Vax, and we agreed to pay $2.0 million of the remaining consideration payable of $4.5 million to the selling shareholders of China Vax. The reduction of the consideration payable of $2.5 million (RMB15.6 million) was recognized as other operating income in 2012.

(3) In 2008, 2009, 2010, 2011 and 2012, other income included the incentive payment received from our depositary in connection with the establishment of the ADR program following our initial public offering and tax refund granted by local governments.

(4) Certain of our PRC operating subsidiaries were entitled to a tax holiday for 2008, 2009, 2010 and 2011. The effect of the tax holiday increased our net income for 2008, 2009, 2010 and 2011 by RMB56.4 million, RMB23.5 million, RMB29.9 million and RMB7.0 million respectively, or RMB0.45, RMB0.20, RMB0.28 and RMB0.06 on the basic per share basis, respectively. None of our PRC subsidiaries was entitled to a tax holiday in 2012.

	Year Ended December 31,				
	2008	2009	2010	2011	2012
			(in percentages)		
Other Consolidated Financial Data					
Gross margin(1)	81.6	82.7	84.0	83.9	82.7
Operating margin(1)	20.5	5.5	10.1	7.0	1.9
Net margin(1)	20.1	1.4	8.1	8.7	2.7

(1) Gross margin, operating margin and net margin represent gross profit, operating profit and net income attributable to our company divided by revenue, respectively.

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	As of December 31,					
	2008 RMB	2009 RMB	2010 RMB	2011 RMB	2012 RMB	2012 $
	(in thousands)					
Selected Consolidated Balance Sheet Data						
Cash	812,814	442,488	273,583	209,850	178,162	28,597
Assets held for sale					90,550	14,534
Accounts and bills receivables, net	748,997	704,321	884,738	1,276,872	1,093,111	175,456
Inventories	95,948	106,655	89,732	126,708	120,932	19,411
Total current assets	1,707,759	1,371,864	1,388,487	1,847,333	1,743,397	279,834
Property, plant and equipment, net	463,059	744,713	836,291	900,746	840,632	134,931
Goodwill and intangible assets, net	453,455	695,267	658,139	648,408	519,334	83,359
Total assets	2,778,222	3,137,902	3,218,252	3,734,117	3,372,663	541,350
Accounts and bills payables	25,219	152,249	49,638	80,570	62,136	9,974
Short-term borrowings and current portion of long-term borrowings	6,000	76,000	360,000	816,150	675,779	108,470
Total current liabilities	335,013	692,865	1,005,846	1,462,547	1,209,518	194,141
Long-term borrowings, excluding current portion	62,000	122,685	19,306		2,000	321
Total shareholders equity	2,301,322	2,207,683	2,054,243	2,193,697	2,072,368	332,638

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 as set forth in the H.10 weekly statistical release of the U.S. Federal Reserve Board, on December 31, 2012, which was RMB6.2301 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 April 19, 2013, the exchange rate, as set forth in the H.10 statistical release of the U.S. Federal Reserve Board, was RMB6.1720 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.

	RMB per U.S. Dollar Exchange Rate			
	Period End	Average(1)	Low	High
	(RMB per $1.00)			

2008	6.8225	6.9193	7.2946	6.7800
2009	6.8259	6.8307	6.8470	6.8176
2010	6.6000	6.7603	6.8330	6.6000
2011	6.2939	6.4475	6.6364	6.2939
2012	6.2301	6.3088	6.3879	6.2221
2012				
October	6.2372	6.2627	6.2877	6.2372
November	6.2265	6.2338	6.2454	6.2221
December	6.2301	6.2328	6.2502	6.2251
2013				
January	6.2186	6.2215	6.2303	6.2134
February	6.2213	6.2323	6.2438	6.2213
March	6.2108	6.2154	6.2246	6.2105
April (through April 19, 2013)	6.1772	6.1927	6.2078	6.1720

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(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

Not Applicable.

C. Reasons for the Offer and Use of Proceeds

Not Applicable.

D. Risk Factors

Risks Related to Our Company

If the proposed going private transaction does not close, our operations after any termination of the transaction may suffer from the effects of business uncertainties resulting from announcement of the transaction, contractual restrictions on our activities during the period in which we are subject to the merger agreement we may enter into, and costs associated with the proposed transaction.

Our board of directors received a non-binding proposal letter from Mr. Jinsheng Ren, New Good Management Limited, Assure Ahead Investments Limited and its affiliates (the Buyer Group) on March 11, 2013, pursuant to which the Buyer Group proproses to acquire all the outstanding ordinary shares of the Company not currently owned by the Buyer Group, for $9.56 per ADS or $4.78 per ordinary share in cash. The Company s board of directors has formed a special committee of independent directors to consider the proposed transaction. No decision has been made by the special committee with respect to the Company s response to the proposed going-private transaction. There can be no assurance that any definitive offer will be made, that any agreement will be executed or that this or any other transaction will be approved or consummated.

Uncertainty about the effect of the proposed going private transaction on our employees, customers, and other parties may have an adverse effect on our business. Such uncertainty may impair our ability to attract, retain, and motivate key personnel, including our executive leadership, and could cause customers, suppliers, financial counterparties, and others to seek to change existing business relationships with us. We may enter into a merger agreement with the Buyer Group if both parties mutually agree upon the terms for the going private transaction. A merger agreement may include covenants to restrict us from making certain acquisitions and investments, from accessing the debt and capital markets, and from taking other specified actions until the proposed merger occurs or the merger agreement terminates. The restrictions may prevent us

from pursuing otherwise attractive business opportunities and taking other actions with respect to our business that we may consider advantageous. We have incurred, and will continue to incur, significant costs, expenses, and fees for professional services and other transaction costs in connection with the proposed going-private transaction. All the fees and costs will be payable by us even if the merger is not completed.

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.

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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 national and provincial medical insurance catalogs or in the national essential drug list, collectively, the Essential Drug List and Reimbursement List.

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.

The penalties imposed on Jiangsu Quanyi could have a material adverse effect on our business, financial condition and results of operations and damage our reputation.

We entered into agreements on May 22, 2009, October 24, 2009 and November 24, 2009 to obtain a controlling equity interest in Jiangsu Yanshen Biological Technology Stock Co., Ltd., which since March 24, 2011 has been renamed to Jiangsu Quanyi Biological Technology Stock Co., Ltd., or Jiangsu Quanyi. After we entered into the share purchase agreements in October and November 2009 to acquire 15% of the equity interest in Jiangsu Quanyi, but prior to the full completion of the transaction, we discovered quality control problems relating to the production of Jiangsu Quanyi s human-use rabies vaccine. On December 3, 2009, the China Food and Drug Administration, or CFDA, issued a public notice announcing the initiation of a comprehensive investigation into quality issues regarding human-use rabies vaccine manufactured by two companies including Jiangsu Quanyi, and ordered Jiangsu Quanyi to halt marketing and production of all products including its human-use rabies vaccine. In April 2010, the Changzhou Food and Drug Administration found that the four batches of human-use rabies vaccine, which were manufactured by Jiangsu Quanyi and released into the market between July and October 2008, had an insufficient amount of active compounds. It was found that prior to our acquisition of Jiangsu Quanyi, illegal activities were conducted at Jiangsu Quanyi, whereby inadequate quality control processes were in place, and there was misrepresentation and avoidance of regulatory inspections, which caused substandard vaccines to be released into the market. On April 27, 2010, the CFDA revoked two new medicine certificates held by Jiangsu Quanyi for its rabies vaccine (vero cell) and freeze-dried human rabies vaccine (vero cell). The Good Manufacturing Practice, or GMP, certificate for its manufacture of human-use rabies vaccine has also been revoked, and the GMP certificate for its manufacture of influenza vaccine expired on February 2, 2010. On May 15, 2010, Jiangsu Quanyi received a notification from the Changzhou Food and Drug Administration, which assessed a fine of RMB25.6 million, consisting of penalties and confiscable revenues from past sales of substandard human-use rabies vaccine, against Jiangsu Quanyi. The notification also stated that Jiangsu Quanyi must bear the cost of patient re-vaccinations of approximately RMB23.0 million. In addition, the People s Court of Tianning District, Changzhou imposed a fine of RMB1.6 million on Jiangsu Quanyi for its past sales of substandard human-use rabies vaccine. On January 24, 2011, the final judgment issued by the Intermediate People s Court of Changzhou imposed an additional penalty of RMB3.0 million on Jiangsu Quanyi. As of December 31, 2012, RMB5.0 million ($0.8 million) of cost of patient re-vaccinations remained unpaid.

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While there have been no reported adverse events related to the vaccine batches in question, we cannot assure you that there will not be adverse events related to these vaccine batches in the future. In addition, employees of Jiangsu Quanyi directly involved in the production of substandard human-use rabies vaccine were prohibited from engaging in the production and marketing of pharmaceutical products for a period of ten years. The proceedings, investigations and relevant sentence as described above could disrupt our business, divert management resources, result in adverse publicity regarding Jiangsu Quanyi, us and the products we sell, which would harm our reputation and result in our customers or potential customers deferring or limiting their purchase of our products, which could have a material adverse effect on our financial condition and results of operations.

We may be involved in litigation, arbitration or other legal proceedings from time to time that require extensive management attention and resources and may be expensive, time-consuming and disruptive.

We entered into agreements in October and November 2009 to acquire Jiangsu Quanyi through the acquisition of the entire equity interest in China Vax, a Cayman Islands company that, as its sole business, held a 15.0% equity interest in Jiangsu Quanyi for cash consideration. As we discovered quality control problems relating to the production of Jiangsu Quanyi s human-use rabies vaccine, a portion of the consideration has not been paid as of the date of this annual report. In October 2010, the selling shareholders of China Vax filed a claim against us for the amount of consideration we have withheld, or RMB28.4 million, and the interest accrued on the withheld amount at the annual rate of 5.0% from February 4, 2010 to the date when the withheld consideration has been fully paid. In March 2012, we reached a settlement agreement with the selling shareholders and former directors of China Vax, and we agreed to pay $2.0 million of the remaining consideration payable of $4.5 million to the selling shareholders of China Vax. During the arbitration proceeding with the former shareholders of China Vax, Jiangsu Quanyi also initiated legal proceeding through its board of supervisor against its former directors, including Zhi Yang and Ying Du, to seek damages. The board of supervisor and these former directors of Jiangsu Quanyi reached settlement with us simultaneously with our settlement with China Vax. The reduction of the consideration payable of $2.5 million (RMB15.6 million) was recognized as other operating income in 2012. In addition, subsequent to our discovery of the quality control problems relating to the production of Jiangsu Quanyi s human-use rabies vaccine, we initiated an arbitration proceeding against former shareholders of Jiangsu Quanyi to seek damages for RMB113.9 million for misrepresentation in connection with their sales of equity interests in Jiangsu Quanyi. Furthermore, Jiangsu Quanyi also initiated legal proceedings through its board of supervisors against certain former directors and their affiliates to seek damages. In June 2011, we reached a settlement agreement with the former shareholders and former directors of Jiangsu Quanyi, under which the former shareholders of Jiangsu Quanyi paid us total cash compensation of RMB50.0 million in 2011.

In August 2011, Shandong Simcere Medgenn Bio-Pharmaceutical Co., Ltd. (Shandong Simcere) filed lawsuits in Beijing against Protgen Ltd. (Protgen), a biotech company with operations in Beijing, and its major shareholder, Mr. Yongzhang Luo, claiming ownership of several patents and patent applications relating to a method of prolonging the half-life of recombinant human endostatin and seeking damages. Mr. Luo acted as the vice chairman of the board, general manager, and chief science officer of Shandong Simcere.

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In December 2011, certain batches of azithromycin granules produced by Nanjing Simcere Dongyuan Pharmaceutical Co., Ltd., or Nanjing Simcere, were found to have failed to comply with applicable standards for pharmaceuticals. As a result, our income from selling such batches of azithromycin granules of RMB0.2 million was confiscated and an additional penalty of RMB0.2 million was also imposed on us. Litigation, arbitration, and other legal proceedings can be expensive, lengthy, disruptive to normal business operations and harmful to our reputation and may require extensive management attention and resources, regardless of their merit. Moreover, we cannot predict the results of such proceedings, and an unfavorable outcome of a lawsuit or proceeding could materially and adversely affect our reputation, business, financial condition, results of operations and prospects.

In addition, we may also become involved in product liability litigation as the development and commercialization of vaccine and other pharmaceutical products entail an inherent risk of harm to patients. If a product liability claim is brought against us, it may, regardless of merit or eventual outcome, result in damage to our reputation, breach of contract with our customers, decreased demand for our products, costly litigation, product recalls, loss of revenues, and the inability to commercialize new products. Our lack of sufficient liability, disruption or other kind of insurance may exacerbate such risks.

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;

- 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.

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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 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.

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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 revenues 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 price, 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 CFDA 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 CFDA is five years. The maximum protection period granted by the CFDA was eight years prior to April 1999, but was later increased to 12 years. As of March 31, 2013, our product Iremod was under a monitoring period which is to expire on August 14, 2016. 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.

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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, 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. 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 collaboration 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 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 continue to seek collaborations with research institutions, universities and biotechnology companies. We cannot assure you that we will be able to enter into collaborative arrangements with research partners on terms acceptable to us. Our inability to enter into such arrangements 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 revenues.

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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 CFDA before they can be marketed and sold in China. The CFDA 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 CFDA. In addition, the CFDA 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 CFDA approval for our future product candidates, or possibly preclude us from obtaining CFDA 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 CFDA 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.

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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 our pharmaceutical products we sell to our distributor customers are then sold to hospitals owned and controlled by counties or higher level government authorities in China, and our vaccines are sold to various levels of Centers for Disease Control, or CDCs, which are controlled by various levels of government authorities in China as well as some vaccine distributors. These hospitals must implement collective tender processes for the purchase of medicines listed in the Essential Drug List and Reimbursement List and medicines that are consumed in large volumes and commonly prescribed for clinical uses. CDCs may also implement collective tender processes for the purchase of our vaccines. These hospitals and CDCs 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 and CDCs. 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 revenues 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 revenues 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.

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We depend on distributors for a substantial portion 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 substantially all of our products (except our vaccines) exclusively to pharmaceutical distributors in China and depend on distributors for a substantial portion of our revenues. We have business relationships directly or indirectly with approximately 1,405 pharmaceutical distributors in China. In each of 2010, 2011 and 2012, no single distributor accounted for, on an individual basis, 10.0% or more of our revenues, and during the same periods, sales to our five largest distributors accounted in aggregate for approximately 17.6%, 17.2% and 16.6% respectively, of our 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.

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 distributors and third-party marketing firms that we contract with to promote our products and brand name, all 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, or in the case of sales of vaccines, to CDCs, we may not be able to effectively manage our sales and marketing employees, as their compensation is primarily linked to their 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.

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The PRC government has launched anti-corruption campaigns and measures from time to time. 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 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 Essential Drug List and Reimbursement List.

Eligible participants in the national basic medical insurance program in China are entitled to reimbursement from the social medical insurance fund for up to the entire cost of medicines that are included in the Essential Drug List and Reimbursement List. See Item 4. Information on the Company B. Business Overview Regulation Reimbursement Under the National Medical Insurance Program. As of March 31, 2013, 36 of our 47 principal products were included in the Essential Drug List or Reimbursement List. Inclusion of a medicine in the Essential Drug List and Reimbursement List 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 Essential Drug List and Reimbursement List based on factors including treatment requirements, frequency of use, effectiveness and price. The Ministry of Human Resources also periodically adjusts medicines from such catalogs. There can be no assurance that our existing products will continue to be included in the Essential Drug List and Reimbursement List. The removal or exclusion of our products from the Essential Drug List and Reimbursement List 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 the tender is successful or not. Our failure to obtain inclusion of our potential products to the Essential Drug List and Reimbursement List 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 except for Hainan Simcere. We do not purchase 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.

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

We had five products that individually contributed over RMB100.0 million ($16.1 million) to our revenues in 2012, which were Bicun, Zailin, Endu, Yingtaiqing and Sinofuan. Sales of these products accounted in aggregate for 69.6% of our revenues in 2012. We expect sales of these limited products 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.

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.

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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 the date of this annual report, 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 s board of directors 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 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 and the chairman of our board of directors, Mr. Hongquan Liu, our Chief executive officer and director, 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.

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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, we have engaged independent third party manufacturers to manufacture three of our pharmaceuticals. Currently, two of our generic pharmaceuticals are still 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 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 CFDA and other regulatory authorities. In addition, adverse experiences with the use of products must be reported to the CFDA and could result in the imposition of market restrictions through labeling changes or in product removal.

Suppliers of certain active and inactive pharmaceutical ingredients and certain packaging materials used in our products are required to obtain CFDA 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 CFDA-approved sources. CFDA 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 CFDA 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.

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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
- &#16