

Simcere Pharmaceutical Group  
Form 20-F  
April 26, 2013  
[Table of Contents](#)

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

---

**FORM 20-F**

---

(Mark One)

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

**OR**

**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**

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

**OR**

**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

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Commission file number: 001-33398

**Sincere 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**

**Fax: (86) 25 8547 7666**

**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)



Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Table of Contents

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.

Yes  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.

Yes  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.

Yes  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).

Yes  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

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

U.S. GAAP

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

Other

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  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).

Yes  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.

Yes  No

---

Table of Contents

**Table of Contents**

INTRODUCTION

PART I

<u>Item 1.</u>	<u>IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u>	4
<u>Item 2.</u>	<u>OFFER STATISTICS AND EXPECTED TIMETABLE</u>	4
<u>Item 3.</u>	<u>KEY INFORMATION</u>	4
<u>Item 4.</u>	<u>INFORMATION ON THE COMPANY</u>	37
<u>Item 4A.</u>	<u>UNRESOLVED STAFF COMMENTS</u>	61
<u>Item 5.</u>	<u>OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	61
<u>Item 6.</u>	<u>DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	92
<u>Item 7.</u>	<u>MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	104
<u>Item 8.</u>	<u>FINANCIAL INFORMATION</u>	106
<u>Item 9.</u>	<u>THE OFFER AND LISTING</u>	107
<u>Item 10.</u>	<u>ADDITIONAL INFORMATION</u>	108
<u>Item 11.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	115
<u>Item 12.</u>	<u>DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	116

PART II

<u>Item 13.</u>	<u>DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES</u>	118
<u>Item 14.</u>	<u>MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS</u>	118
<u>Item 15.</u>	<u>CONTROLS AND PROCEDURES</u>	118
<u>Item 16.</u>	<u>[RESERVED]</u>	121
<u>Item 16A.</u>	<u>AUDIT COMMITTEE FINANCIAL EXPERT</u>	121
<u>Item 16B.</u>	<u>CODE OF ETHICS</u>	121
<u>Item 16C.</u>	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	121
<u>Item 16D.</u>	<u>EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	122
<u>Item 16E.</u>	<u>PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	122
<u>Item 16F.</u>	<u>CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT</u>	123
<u>Item 16G.</u>	<u>CORPORATE GOVERNANCE</u>	123
<u>Item 16H.</u>	<u>MINE SAFETY DISCLOSURE</u>	123

PART III

<u>Item 17.</u>	<u>FINANCIAL STATEMENTS</u>	124
<u>Item 18.</u>	<u>FINANCIAL STATEMENTS</u>	124
<u>Item 19.</u>	<u>EXHIBITS</u>	124

Table of Contents

**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.

Table of Contents**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.

	2008	2009	Year Ended December 31,		2012	2012
	RMB	RMB	2010	2011	RMB	\$
	(in thousands, except share and ADS data)					
<b>Selected Consolidated Statement of Comprehensive Income Data</b>						
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)



Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

Table of Contents

(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 depository 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.

	2008	2009	Year Ended December 31, 2010 (in percentages)	2011	2012
<b>Other Consolidated Financial Data</b>					
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.

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Table of Contents

	2008 RMB	2009 RMB	As of December 31,		2012 RMB	2012 \$
			2010 RMB	2011 RMB		
(in thousands)						
<b>Selected Consolidated Balance Sheet Data</b>						
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.

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

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

Table of Contents

---

(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 proposes 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

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

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.***

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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.



Table of Contents

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.

Table of Contents

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;

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- 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.

Table of Contents

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.

Table of Contents

***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

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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.

Table of Contents

***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

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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.



Table of Contents

***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.

Table of Contents

***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;

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- 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.

Table of Contents

***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.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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.

Table of Contents

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.



Table of Contents

*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



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- 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.

Table of Contents

***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.



Table of Contents

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.

Table of Contents

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

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

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

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

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

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

We may, from time to time, need to raise funds as part of our business operations if our expenditures exceed our expectations. This could occur for a number of reasons, including but not limited to:

- we determine to devote significant amount of financial resources to the research and development of projects that we believe to have significant commercialization potential;
- we determine to acquire or license rights to additional product candidates or new technologies;
- some or all of our product candidates fail in clinical trials or pre-clinical studies or prove to be not as commercially promising as we expect and we are forced to develop or acquire additional product candidates;
- our product candidates require more extensive clinical or pre-clinical testing or clinical trials of these product candidates take longer to complete than we currently expect; or
- we determine or are required to conduct more high-throughput screening than expected against current or additional disease targets to develop additional product candidates.

Table of Contents

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

- our future financial condition, results of operations and cash flows;
- general market conditions for capital-raising activities by pharmaceutical companies; and
- economic, political and other conditions in China and elsewhere.

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

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

As of December 31, 2012, our net intangible assets including in-process research and development ( IPR&D ) amounted to RMB234.7 million (\$37.7 million), representing 7.0% of our total assets, and goodwill amounted to RMB284.6 million (\$45.7 million), representing 8.4% of our total assets. Our intangible assets primarily consisted of customer relationships, developed technologies, product trademarks and IPR&D that we acquired in connection with our acquisition of 90.0% of the equity interest in Shandong Simcere in 2006 and 2007, a 51.0% equity interest in Jilin Boda Pharmaceutical Co., Ltd., or Jilin Boda, in 2007, an 85.7% equity interest in Nanjing Tung Chit Pharmaceutical Company Limited, or Nanjing Tung Chit, in 2007, a 70.0% equity interest in Wuhu Simcere Zhong Ren Pharmaceutical Co., Ltd., or Simcere Zhong Ren, in 2008, and 52.5% equity interest in Jiangsu Quanyi in 2009. Developed technology represents the right to use, manufacture, market and sell the acquired products as well as their related invention patents in the PRC or the United States, as the case may be, while trademarks represent the right by the trademark registrant to use the registered trademark and to protect products from infringement. We estimated the fair value of the customer relationships, developed technologies, trademarks and IPR&D of the acquired products using their respective present values of projected cash flows based on assumptions with respect to the growth rate of our revenues from sales, the earnings before interest and tax margin derived from sales, the discount rate selected to measure the risks inherent in future cash flows and our assessment of the product life cycle. We also took into consideration the competitive trends that may affect these products sales, including consideration of any technical, legal, regulatory, and economic barriers to entry. See Item 5. Operating and Financial Review and Prospects A. Operating Results Critical Accounting Policies Long-Lived Assets and Goodwill. We determined the useful life of the developed technology of an acquired product by considering the remaining protection period of such product s patent in China and the expected competitive trend in the PRC market. As of December 31, 2012, we performed goodwill impairment analysis of our two reporting units, a pharmaceutical reporting unit and a vaccine reporting unit. Based on this analysis, RMB25.3 million (\$4.1 million) of goodwill impairment loss was recognized in 2012. We also performed impairment analysis on our IPR&D, and an impairment loss on IPR&D of RMB70.1 million (\$11.2 million) was recognized in 2012. See Item 5. Operating and Financial Review and Prospects Acquisitions.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Future events such as market acceptance of the acquired products, introduction of superior pharmaceuticals by our competitors, regulatory actions, safety concerns as to our pharmaceuticals or vaccines, and challenges to and infringement of our intellectual property rights, could have a material impact on our key assumptions in determining the fair value of the developed technology of the acquired products. This in turn could result in further write-downs of our intangible assets or goodwill, or a change in the useful lives of our intangible assets. Future impairment of our intangible assets or goodwill, or change in useful lives of our intangible assets, could decrease our net income, which would have a material adverse impact on our financial condition and results of operations.



Table of Contents

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

As of the date of this annual report, we had a number of shareholders other than public shareholders holding our ordinary shares in the form of ADSs, including New Good Management Limited, a company beneficially owned by 8 individuals, including certain of our senior management, and controlled by Mr. Jinsheng Ren, our founder and chairman of our board of directors; Assure Ahead Investments Limited, an investment vehicle owned and controlled by a group of financial investors; and King View Development International Limited, an investment vehicle owned and controlled by Trustbridge Partners, a private equity fund. As of April 19, 2013, New Good Management Limited owned approximately 36.0% of our outstanding share capital, and Assure Ahead Investments Limited, King View Development International Limited and Fosun Industrial Co., Ltd. owned 17.5%, 11.5% and 7.8% of our outstanding share capital, respectively. As of April 19, 2013, Amy Liu, an individual shareholder, owned approximately 6.5% of our outstanding share capital. As such, they have substantial influence over our business, including decisions regarding mergers, consolidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions. This concentration of ownership may discourage, delay or prevent a change in control of our company, which could deprive our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and might reduce the price of our ADSs.

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

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

***We rely on third parties to provide raw materials and any quality defect may have an adverse impact on our products, our business and results of operations.***

We source raw materials such as capsules, as well as packaging materials, from various independent suppliers in China. Our principal packaging materials include glass ampules for injection pharmaceuticals, plastic bottles for capsule and tablet pharmaceuticals, and external packaging and printed instructions for all of our pharmaceuticals. The principal raw materials used for our vaccine products are egg embryos, which were supplied by two domestic manufacturers. Although we have internal quality control system to control the quality of purchased raw materials, we may not be able to identify all quality defects. If any quality defect of the raw materials that we purchase happens, our products, our business and results of operations will be adversely affected.

***Labor laws in the PRC may adversely affect our results of operations.***

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

On June 29, 2007, the PRC government promulgated a new labor law, namely, the Labor Contract Law of the PRC, or the Labor Contract Law, which became effective on January 1, 2008. On December 28, 2012, the PRC government promulgated an amendment to the Labor Contract Law of the PRC, which will become effective on July 1, 2013. The Implementation Rules of the Labor Contract Law was subsequently promulgated and became effective on September 18, 2008. The PRC government also promulgated the Law on Mediation and Arbitration of Labor Disputes on December 29, 2007 that came into effect on May 1, 2008. These labor laws and regulations impose greater liabilities on employers and significantly impact the cost of an employer's decision to reduce its workforce. Further, they require certain terminations to be based upon seniority but not merit. In the event we decide to significantly change or decrease our workforce, the Labor Contract Law could adversely affect our ability to enact such changes in a manner that is most advantageous to our business or in a timely and cost effective manner, thus materially and adversely affecting our financial condition and results of operations.

Table of Contents

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

We adopted a share incentive plan on November 13, 2006. We granted 10,000,000, 1,045,000, 400,000, 100,000 and 978,000 share options under our 2006 share incentive plan on November 15, 2006, March 29, 2007, May 5, 2008, December 24, 2008 and September 1, 2010, respectively. On July 31, 2008, our shareholders approved our 2008 share incentive plan under which we are authorized to issue up to 6,250,000 ordinary shares upon exercise of awards granted thereunder. On April 15, 2009, our compensation committee approved a share option exchange program that offered our eligible employees and directors the right to exchange vested and unvested outstanding share options to purchase our ordinary shares under the 2006 Share Incentive Plan for restricted shares (which are referred to in the notes related to the consolidated financial statements included elsewhere in this annual report on Form 20-F as nonvested shares per FASB ASC, *Compensation Stock Compensation*). The exchange ratio was determined based on the fair value of replacement restricted shares so that the fair value of the replacement restricted shares to be issued upon exchange would be approximately equivalent to the fair value of the share options surrendered by an individual. In addition, these replacement restricted shares are subject to substantially the same vesting schedule as the options that were validly tendered in the exchange offer. The exchange of the share option awards for restricted shares was accounted for as a modification for awards which involves a cancellation of the original award and an issuance of a new award. The replacement restricted shares were granted on May 7, 2009. The effect of this award modification on share-based compensation expense over the remaining requisite service period was insignificant.

On October 14, 2009 and December 4, 2009, we granted 200,000 restricted shares and 40,000 restricted shares, respectively, to our officers and key employees under our 2006 share incentive plan. In 2010, we granted 870,000 restricted shares in aggregate to our officers and key employees under our 2006 share incentive plan, including 480,000 restricted shares granted on March 9, 2010 to our independent directors and president. In 2011, we granted 364,000 restricted shares to our officers and key employees under our 2006 share incentive plan. In 2012, we granted 4,140,000 restricted shares to our directors and key employees under our 2006 share incentive plan. In 2012, we also granted 2,000,000 restricted shares to one of our directors under the 2008 share incentive plan.

We recognize, as an expense, the fair value of share options and other share-based compensation to employees based on the fair value of equity awards on the date of the grant, with the compensation expense recognized over the period in which the recipient is required to provide service in exchange for the equity award. If we grant additional options, restricted shares and other equity incentives in the future, we could incur significant compensation charges and our net income could be adversely affected.

Table of Contents

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

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

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

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

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

We believe that we were not a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for our taxable year ended December 31, 2011, and we do not expect to become one for our current taxable year or in the future, although there can be no assurance in this regard. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. For this purpose, the value of our assets may be determined in large part by the market price of our ADSs, which is likely to fluctuate. If we are treated as a PFIC for any taxable year during which U.S. holders hold ADSs or ordinary shares, certain adverse U.S. federal income tax consequences could apply to such U.S. holders. See Taxation United States Federal Income Taxation Passive Foreign Investment Company.

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

Voting at any of our shareholder meetings is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of the meeting or by any shareholder present in person or by proxy. If a poll is demanded, each shareholder present in person or by proxy will have one vote for each ordinary share registered in his name. If a poll is not demanded, voting will be by show of hands and each shareholder present in

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

Table of Contents

***Our independent registered public accounting firm's audit documentation related to their audit reports included in this annual report may be located in the Peoples' Republic of China. The Public Company Accounting Oversight Board currently cannot inspect audit documentation located in China and, as such, you may be deprived of the benefits of such inspection.***

Our independent registered public accounting firm that issues the audit reports included in our annual reports filed with the U.S. Securities and Exchange Commission, as auditors of companies that are traded publicly in the United States and a firm registered with the Public Company Accounting Oversight Board (United States) (the PCAOB), is required by the laws of the United States to undergo regular inspections by the PCAOB to assess its compliance with the applicable laws of the United States and professional standards. Our operations are principally conducted in the Peoples' Republic of China, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities. Accordingly, any audit documentation located in China related to our independent registered public accounting firm's reports included in our filings with the U.S. Securities and Exchange Commission is not currently inspected by the PCAOB.

Inspections conducted by the PCAOB outside of China have identified deficiencies in those firms' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. This lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating audit documentation located in China and its related quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections.

The inability of the PCAOB to conduct inspections in China makes it more difficult to evaluate the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures as compared to audits outside of China that are subject to PCAOB inspections. Investors may lose confidence in our reported financial information and procedures and the quality of our financial statements.

**Risks Related to Our Industry**

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

Our business and revenue growth primarily depend on the size and growth of the market for pharmaceutical products in China. As a result, our revenues and profitability may be negatively affected by changes in national, regional or local economic conditions and consumer confidence in China. In particular, as we focus our expansion of retail stores in metropolitan markets, where living standards and consumer purchasing power are higher than rural areas, we are especially susceptible to changes in economic conditions, consumer confidence and customer preferences of the urban Chinese population. External factors beyond our control that affect consumer confidence include unemployment rates, levels of personal disposable income, national, regional or local economic conditions and acts of war or terrorism. Changes in economic conditions and consumer confidence could adversely affect consumer preferences, purchasing power and spending patterns. In addition, we cannot assure you that market conditions will continue to improve in the near future or that our results will not be materially and adversely affected. In addition, acts of war or terrorism may cause damage to our facilities, disrupt the supply of the products and services we offer in our stores or adversely impact consumer demand. Any of these factors could have a material adverse effect on our business, financial condition and results of operations.

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

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

Table of Contents

Many of our existing and potential competitors may have greater financial, technical, manufacturing and other resources than we do. In addition, certain competitors which were established by multinational pharmaceutical companies have more extensive research and development and technical capabilities than we do. Furthermore, China's industry reforms aimed to meet the World Trade Organization, or the WTO, requirements may foster increased competition from multinational pharmaceutical companies. Such competitors may also have greater brand name recognition, more established distribution networks, larger customer bases or more extensive knowledge of our target markets. Our competitors' greater size in some cases provides them with a competitive advantage with respect to manufacturing costs because of their economies of scale and their ability to purchase raw materials at lower prices. As a result, they may be able to devote greater resources to the research, development, promotion and sale of their products or respond more quickly to evolving industry standards and changes in market conditions than we can. In addition, certain of our competitors may adopt low-margin sales strategies and compete against us based on lower prices. Our failure to adapt to changing market conditions and to compete successfully with existing or new competitors may materially and adversely affect our financial condition and results of operations.

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

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

Certain of our pharmaceutical products, primarily those included in the Essential Drug List and Reimbursement List, are subject to price controls in the form of fixed retail prices or retail price ceilings. See Item 4. Information on the Company B. Business Overview Regulation Price Controls. In addition, the maximum retail prices of products that are included in the Essential Drug List and Reimbursement List are also subject to periodic downward adjustments as the PRC government authorities aim to make pharmaceuticals more affordable to the general public. However, PRC government authorities impose no control over the prices at which pharmaceutical manufacturers sell their products to their distributors. Since May 1998, the relevant PRC government authorities have ordered price reductions of various pharmaceuticals 31 times. The latest price reductions occurred on January 5, 2013. The retail price ceilings of our major products Bicun, Anxin and Shufutan, were adjusted downward, but will not significantly affect the actual sales price. In the long term, the prices at which pharmaceutical manufacturers in China sell their products to distributors, including the prices of our products, will be affected by the relevant fixed retail prices or retail price ceilings. Government price controls, especially downward price adjustments, may have an adverse effect on our revenues and profitability.

***We may be adversely affected by the sales and marketing performance of our joint venture with Merck & Co., Inc.***

The sales and marketing of some of our products are conducted by our joint venture with Merck & Co., Inc., which primarily include Xinta and Shufutan. Maintaining and promoting such products' brands will depend largely on the success of the joint venture's sales and marketing efforts. In addition, if the joint venture fails to comply with relevant laws and regulations in the promoting and marketing of these products, our public image and reputation could be tarnished by negative publicity and our results of operations may be adversely affected.



Table of Contents

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

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

We have obtained permits and licenses and GMP certifications required for the manufacture of our pharmaceutical products. In addition, we have obtained permits, licenses and Good Supply Practice, or GSP, certifications for the distribution of our products. Each of these permits and licenses held by us is valid for five years and subject to periodic renewal and/or reassessment by the relevant PRC government authorities and the standards of compliance required in relation thereto may from time to time be subject to changes. For example, our current pharmaceutical manufacturing permits for each of Simcere Pharmaceutical Co., Ltd., or Hainan Simcere, Nanjing Simcere, Shandong Simcere, Jilin Boda, and Simcere Zhong Ren, Jiangsu Vaxtec will all expire on December 31, 2015. The 21 GMP certificates for our six manufacturing facilities will expire between May 2013 and April 2018. In 2011, our branded generic anti-diarrheal pharmaceutical Biqi passed the EU-GMP inspection and received EU-GMP certification from the Finnish Medicines Agency. We also have one GSP certificate held by our distribution subsidiary which will expire in July 2013.

At the time we acquired Jiangsu Quanyi, its core products included an influenza vaccine and a human-use rabies vaccine (vero cell). Jiangsu Quanyi had also received a new medicine certificate from the CFDA for its freeze-dried human rabies vaccine (vero cell) and had completed clinical trials of its purified hepatitis A inactivated vaccine (vero cell) while CFDA approval for its purified hepatitis A inactivated vaccine (vero cell) and GMP certification for the associated new manufacturing facility were pending. However, since the discovery of the substandard vaccine manufactured by Jiangsu Quanyi prior to our acquisition, the two new medicine certificates held by Jiangsu Quanyi for its rabies vaccine (vero cell) and freeze-dried human rabies vaccine (vero cell) have been revoked. The 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.

In August 2011, Jiangsu Quanyi injected certain machineries and equipment as paid-in capital into Jiangsu Vaxtec Biological Pharmaceutical R&D Co., Ltd., then renamed to Jiangsu Simcere Vaxtec Biological Pharmaceutical Co., Ltd. in June 2011, or Jiangsu Vaxtec, the wholly owned subsidiary of Jiangsu Quanyi. Jiangsu Quanyi transferred the vaccine business to Jiangsu Vaxtec and Jiangsu Vaxtec received the GMP certification of influenza vaccine on March 14, 2013. We intend to apply for the renewal of our permits and licenses when required by applicable laws and regulations. See Item 4. Information on the Company B. Business Overview Regulation. Any failure by us to obtain such GMP certifications may have a material adverse effect on the operation of our business, and prevent us from continuing to carry on our business. Furthermore, any changes in compliance standards, or any new laws or regulations may prohibit or render it more restrictive for us to conduct our business or may increase our compliance costs, which may adversely affect our operations or profitability.

**Risks Related to Doing Business in China**

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

The PRC legal system is a civil law system based on written statutes. Unlike in the common law system, prior court decisions may be cited for reference but have limited precedential value. Since 1979, PRC legislation and regulations have significantly enhanced the protections afforded

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

Table of Contents

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

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

- the degree of government involvement;
- the level of development;
- the growth rate;
- the control of foreign exchange;
- access to financing; and
- the allocation of resources.

While the Chinese economy has grown significantly in the past, the growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures benefit the overall Chinese economy, but may also have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us.

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



Table of Contents

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

We are a holding company with no material operations. We conduct our operations mainly through our PRC subsidiaries. As a holding company, we may depend on the receipt of dividends and the interest and principal payments on intercompany loans or advances from our subsidiaries to satisfy our obligations, including our obligations to pay any dividends we may declare. The ability of our subsidiaries to pay dividends and make payments on intercompany loans or advances to their shareholders is subject to, among other things, distributable earnings, reserve funds, cash flow conditions, restrictions contained in the articles of association of our subsidiaries, applicable laws and restrictions contained in the debt instruments or agreements of such subsidiaries. In addition, if any of our subsidiaries raises capital by issuing equity securities to third parties, dividends declared and paid with respect to such equity securities would be available to us. These restrictions could reduce the amounts that we receive from our subsidiaries, which could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our businesses, pay dividends, service our debts, or otherwise fund and conduct our business.

PRC laws and regulations permit payment of dividends only out of accumulated profits as determined in accordance with PRC accounting standards and regulations and such profits differ from profits determined in accordance with U.S. GAAP in certain significant respects, including the use of different bases of recognition of revenue and expenses. Our PRC subsidiaries are also required to set aside a portion of their after-tax profits according to PRC accounting standards and regulations to fund certain reserves that are not distributable as cash dividends. In practice, our PRC subsidiaries are also required to obtain a required tax clearance with the local tax bureau and complete the corresponding foreign exchange procedures before paying any dividends. Under the Corporate Income Tax Law of the PRC, or the CIT law and its implementing regulations, PRC income tax at the rate of 10% is applicable to dividends payable for earnings derived since January 1, 2008 by PRC enterprises to non-resident enterprises (enterprises that do not have an establishment or place of business in China or that have such an establishment or place of business in China but for which the relevant income is not effectively connected with such establishment or place of business), subject to any lower withholding tax rate as may be contained in any income tax treaty or agreement that China has entered into with the government of the jurisdiction where such non-resident enterprises were incorporated. If we are considered as a non-resident enterprise under PRC tax law, any dividend that we receive from our PRC subsidiaries may be subject to PRC taxation at the 10% rate.

Furthermore, we may from time to time resort to offshore shareholder loans, rather than equity contribution, to our PRC subsidiaries to finance their operations. In such events, the market interest rates that our PRC subsidiaries can pay with respect to offshore loans generally may not exceed comparable interest rates in the international finance markets. Our PRC subsidiaries are also required to pay a 10% (or 7% if the interest is paid to a Hong Kong resident under certain circumstances) withholding tax on our behalf on the interest paid under any shareholder loan. Prior to payment of interest and principal on any such shareholder loan, the PRC subsidiaries (as foreign-invested enterprises in China) must present evidence of payment of the withholding tax on the interest payable on any such shareholder loan and evidence of registration with SAFE, as well as any other documents that SAFE or its local branch may require.

Table of Contents

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

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

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

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

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

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

The CIT law, provides that a maximum income tax rate of 10% may be applicable to dividends payable to non-PRC investors that are non-resident enterprises to the extent such dividends are derived from sources within the PRC. We are a Cayman Islands holding company and State Good Group Limited, or SGG, is a British Virgin Islands intermediate holding company. Substantially all of our income may be derived from dividends we receive from our operating subsidiaries located in the PRC. Thus, dividends indirectly paid to us by our subsidiaries in China, if any, may be subject to the 10% income tax if SGG is considered as a non-resident enterprise under the CIT law. We have not provided for income taxes on accumulated earnings generated by our PRC subsidiaries from 2008 to 2012 because we plan to indefinitely reinvest these earnings in the PRC. If SGG is required under the CIT law to pay income tax with respect to any dividends we receive from our subsidiaries, it will materially and adversely affect the amount of dividends, if any, we may pay to our shareholders and ADS holders.



Table of Contents

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

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

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

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

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

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

There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which could result in a further and more significant appreciation of the Renminbi against the U.S. dollar. As we rely on dividends paid to us by our PRC operating subsidiaries, any significant revaluation of the Renminbi may have a material adverse effect on the value of, and any dividends payable on, our ADSs in foreign currency terms. Appreciation of the Renminbi against the U.S. dollar would have an adverse effect on the Renminbi amount we would receive from the conversion. Conversely, if we decide to convert our Renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the Renminbi would have a negative effect on the U.S. dollar amount available to us. In addition, appreciation or depreciation in the value of the Renminbi relative to the



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations.

Table of Contents

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

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

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

Our business could be adversely affected by the effects of avian flu, SARS, swine flu or another epidemic or outbreak. During April and May 2009, there have been outbreaks of highly pathogenic swine flu, caused by the H1N1A virus, in certain regions of the world, including parts of Asia. In 2007 and early 2008, there were reports of outbreaks of a highly pathogenic avian flu, caused by the H5N1 virus, in certain regions of Asia and Europe. In 2005 and 2006, there were reports on the occurrences of avian flu in various parts of China, including a few confirmed human cases. An outbreak of avian flu in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, particularly in Asia. Additionally, any recurrence of SARS, a highly contagious form of atypical pneumonia, similar to the occurrence in 2003 which affected China, Hong Kong, Taiwan, Singapore, Vietnam and certain other countries, would also have similar adverse effects. These outbreaks of contagious diseases, and other adverse public health developments in China, would have a material adverse effect on our business operations. These could include restrictions on our ability to travel or to ship our products within China, as well as cause temporary closure of our manufacturing facilities. Such closures or travel or shipment restrictions would severely disrupt our business operations and adversely affect our financial condition and results of operations. We have not adopted any written preventive measures or contingency plans to combat any future outbreak of avian flu, SARS, swine flu or any other epidemic.

Table of Contents

**Risks Related to Our ADSs**

*The market price for our ADSs may be volatile.*

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

- announcements of technological or competitive developments;
- regulatory developments in China affecting us, our customers or our competitors;
- announcements regarding patent litigation or the issuance of patents to us or our competitors;
- actual or anticipated fluctuations in our quarterly operating results;
- changes in financial estimates by securities research analysts;
- changes in the economic performance or market valuations of other pharmaceutical companies;
- addition or departure of our executive officers and key research personnel;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; and
- sales or perceived sales of additional ordinary shares or ADSs.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

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

Additional sales of our ADSs or ordinary shares, including ADSs or ordinary shares issuable upon the exercise of our outstanding stock options, in the public market, or the perception that these sales could occur, could cause the market price of our ADSs to decline. If our shareholders sell substantial amounts of our ADSs, including those issued upon the exercise of outstanding options, in the public market, the market price of our ADSs could fall. Such sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate. If any existing shareholder or shareholders sell a substantial amount of ordinary shares, the prevailing market price for our ADSs could be adversely affected.

In addition, we may issue additional ordinary shares or ADSs for future acquisitions. If we pay for our future acquisitions in whole or in part with additionally issued ordinary shares or ADSs, your ownership interests in our company would be diluted and this, in turn, could have a material adverse effect on the price of our ADSs.

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

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

Table of Contents

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

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

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

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

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

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

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

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act, or exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.



Table of Contents

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

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

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

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

***You may have difficulty enforcing judgments obtained against us.***

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

Table of Contents

**Item 4. INFORMATION ON THE COMPANY**

*A. History and Development of the Company*

Our predecessor entity, Hainan Simcere Investment Group Ltd., or Simcere Investment, was a PRC company that held a group of pharmaceutical companies that develops, manufactures and markets a range of branded generic and innovative pharmaceuticals. To raise capital from investors outside of China, we established State Good Group Limited, or SGG, in the British Virgin Islands on October 12, 2005. Our operating subsidiaries were transferred to SGG in March 2006 as part of a series of corporate reorganization activities. We incorporated Simcere Pharmaceutical Group in the Cayman Islands as a listing vehicle on August 4, 2006. Simcere Pharmaceutical Group became our ultimate holding company when it issued ordinary shares to existing shareholders of SGG on September 29, 2006, in exchange for the respective ordinary shares that these shareholders held in SGG.

Subsequent to our initial public offering on April 20, 2007, we have engaged in a number of acquisitions to strengthen our product portfolio, especially as to first-to-market generic and innovative pharmaceuticals in China. See Item 5. Operating and Financial Reviews and Prospects A. Operating Results Acquisitions.

*B. Business Overview*

We are a leading manufacturer and supplier of branded pharmaceuticals in the fast growing China market. We focus our strategy on the development of first-to-market generic and innovative pharmaceuticals, and have introduced a first-to-market generic anti-stroke medication under the brand name Bicun, a 5-FU sustained release implant under the brand name Sinofuan, Anxin, Jiebaishu and an innovative anti-cancer medication under the brand name Endu. We currently manufacture and sell 47 principal pharmaceutical products. In addition, we have obtained approvals from the CFDA to manufacture and sell over 223 other products. In 2012, we received clinical trial approval from the CFDA for four investigational new drugs, or INDs, applying for Category I new drug. As of March 31, 2013, we also had over 11 product candidates in various stages of development, including treatments for cancer and cardiovascular diseases.

Our innovative anti-cancer medication Endu has been granted an invention patent in China and an invention patent in the United States, and was the first recombinant human endostatin injection approved for sale in China. Recombinant human endostatin is a genetically engineered protein that interferes with the growth of blood vessels to a tumor, thereby starving and preventing the growth of tumor cells. Our generic anti-stroke medication Bicun was the first edaravone injection, a type of neuroprotective pharmaceutical compound, approved for sale in China. Our generic amoxicillin granule antibiotic, marketed under the brand name Zailin, was recognized as a China Well-Known Trademark in 2004, and acquired the qualification to premium price and our anti-inflammatory pain relievers for the treatment of rheumatoid arthritis and osteoarthritis, marketed under the brand name Yingtaiqing, was recognized as a China Well-Known Trademark in 2008, and acquired the qualification to premium price. Our generic anti-stroke medication Bicun was recognized as a China Well-Known Trademark in 2011 and Simcere was also recognized as a China Well-Known Trademark in 2011 by the State Administration for Industry and Commerce of PRC. Furthermore, our medication Sinofuan, a 5-Fu sustained-released implant for the treatment of cancer which we obtained from our successful acquisition of Simcere Zhong Ren, is the first and the only dosage form of sustained-release implant approved by the CFDA, and our generic anti-infection medication Anxin, a new product that we introduced in 2008, was the first biapenem injection, a type of carbapenem, approved for sale in China.



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

In 2011, our branded generic anti-diarrheal pharmaceutical Biqi passed the EU-GMP inspection and received EU-GMP certification from the Finnish Medicines Agency.

In January 2012, we officially announced the launch of sale of Iremod on the China market. Iremod, which was independently developed by us, is the first Iguratimod drug on the global market. It is an innovative new molecular formula in the category of Disease Modifying Anti-rheumatic Drugs ( DMARDS ), which are primarily used in the treatment of active rheumatoid arthritis.

Table of Contents

We commenced operations in March 1995 as a distributor of pharmaceutical products, and since then we have established an extensive distribution network in China that we now use to market, sell and distribute our own pharmaceutical products. We sell our products (except our vaccines) exclusively to regional distributors, who then sell them to local distributors, hospitals and retail pharmacies throughout China. Our marketing team leverages the reputation of our Simcere brand name and our well-known branded pharmaceuticals to cross-sell our other pharmaceuticals. We also have dedicated brand management, market research and sales support teams to further enhance the effectiveness of these marketing efforts. On November 29, 2011, Simcere, a proprietary brand of the Simcere Pharmaceutical Group, was designated as a Chinese Famous Trademark by the Trademark Appeal Board of the State Administration for Industry & Commerce.

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

In July 2011, we entered into a framework agreement to establish a novel and innovative strategic partnership with Merck & Co., Inc. or Merck, which through an affiliate and known as MSD outside the United States and Canada, focused on serving China's rapidly expanding health care needs by providing significantly improved access to quality medicines in major therapeutic areas. The partnership includes the establishment of an equity joint venture that will be owned 51% by an affiliate of Merck, and 49% by us or one of our affiliates. By entering into the framework agreement, we intend to establish the basic framework of cooperation between the two companies to co-promote and/or distribute certain medicines. We also agreed with Merck to explore the possibility of establishing a second joint venture focused on the manufacturing of certain medicines.

**Our Products**

We currently manufacture and sell 47 principal pharmaceuticals marketed under various brands. Of these products, 41 are prescription pharmaceuticals and six are over-the-counter, or OTC, pharmaceuticals. In addition, we are also the exclusive distributor of Yingtaiqing-branded generic diclofenac sodium sustained-release capsules and the Faneng-branded generic alfacalcidol soft capsules, both of which are prescription pharmaceuticals manufactured by independent third parties. Furthermore, we have obtained approvals from the CFDA to manufacture and sell over 223 other products.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

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

Product Category	Number of Products	Major Products	Brands
Antibacterial and Antiviral	17	Amoxicillin granules, capsules and tablets; amoxicillin with clavulanate potassium granules, tablets and injection; biapenem injection; cefaclor dry suspension; azithromycin granules;	Zailin, Anqi, Anxin, Zaike, Zaiqi
Anti-cancer	6	Recombinant human endostatin injection; nedaplatin injection; pemetrexed disodium for injection and fluorouracil implants; and palonosetron hydrochloride injection	Endu, Jiebaishu, Jiebaili, Sinofuan and Lowvo
Anti-Allergic	2	Clemastine fumarate capsules and clemastine fumarate dry suspension	Langjing
Anti-Osteoporosis	2	Alfacalcidol soft capsules	Faneng
Cardiovascular and Cerebrovascular	7	Edaravone injection; sumatriptan succinate tablets; levamlodipine besylate tablets; and rosuvastatin calcium tablets	Bicun, Yidasheng, Youshu, Xinta and Shufutan
Digestive Conditions	3	Smectite powder; and aldioxa tablets	Biqi and Odijia
Non-Steroidal Anti-Inflammatory	5	Diclofenac sodium sustained-release capsules and gelatin; Icuratimod Tablets	Yingtaiqing and Iremod
Respiratory System	3	Herbal medicine used for the treatment of cough in liquids and tablets; compound zinc gluconate	Simcere Kechuanning, Zaikang
Urinary Conditions	1	Naftopidil tablets	Zaichang
Others	1	Various herbal oral solutions	Chengyuan

Our innovative pharmaceutical Endu, or recombinant human endostatin, has been granted an invention patent in China and was the first recombinant human endostatin injection approved for manufacture and sale in China and has been approved for the treatment of Non-small Cell Lung Cancer, or NSCLC. Recombinant human endostatin is a genetically engineered protein that interferes with the growth of blood vessels to a tumor, thereby starving and preventing the growth of tumor cells. In 2012, revenues of Endu amounted to RMB271.2 million (\$43.5 million), which accounted for 13.0% of our revenues for the year.

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

These clinical trials showed that the median survival time of the Endu group was approximately five months longer than that of the control group and one year survival rates of the Endu group was 62.8% compared to 31.5% for the control group. The CFDA granted the new medicine certificate for Endu in September 2005 and the relevant approvals to manufacture and sell Endu in March 2006 to Shandong Simcere, a pharmaceutical company founded by Dr. Luo that held an invention patent in China on Endu granted on January 18, 2006. See Item 3. Key Information D. Risk Factors Risks Related to our Company We may be involved in litigation, arbitration or other legal proceedings from time to

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

time that require extensive management attention and resources and may be expensive, time-consuming and disruptive.

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

Table of Contents

We have an in-house research and development team specializing in anti-cancer drugs, know-how and technologies that will enable us to engage in research and development of other indications for Endu, and an existing GMP-approved manufacturing facility for the production of Endu. As part of our ongoing efforts to monitor the efficacy and any adverse reactions to Endu, we started the Phase IV clinical trials for Endu on November 10, 2006. This trial involved approximately 154 hospitals in China in which 2,725 patients were enrolled in the trials and was completed in two-and-a-half years. On March 30, 2010, the final result of the trial was publicly released, which further confirmed the efficacy and safety of Endu combined with chemotherapy in the treatment of non-small-cell lung cancer at advanced stages. The Phase IV clinical trials verified the data collected from previous clinical trials of Endu, and in particular, the clinical benefit rate and the one-year survival rate. The Phase IV clinical trials found no significant difference in efficacy of Endu combined with different first-line chemotherapy regimens, and also no significant increase in adverse effects of chemotherapy when the use of Endu was combined, which indicated the safety of combining Endu with forms of chemotherapy that are beneficial to a greater number of patients.

We are also engaged in various research and development efforts to maximize the commercial potential of Endu. For example, we are also researching other potential indications for Endu as well as on expanding the scope of use for Endu outside of chemotherapy. In addition, we are working to improve the delivery method of Endu for increased ease of use.

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

***Our Principal Branded Generic Pharmaceuticals***

In addition to Endu, we currently market and sell the following principal branded generic pharmaceutical products, each of which contributed over RMB100.0 million (\$16.1 million) to our revenues in 2012 and in aggregate accounted for 56.6% of our revenues in 2012:

- Bicun (edaravone injection);
  
- Zailin (amoxicillin capsules, dispersible tablets, granules and injection);
  
- Yingtaiqing (diclofenac sodium sustained-release capsules and gelatin);and
  
- Sinofuan (anti-tumor implants).

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

**Bicun.** Bicun is our prescription edaravone injection pharmaceutical for the treatment of strokes. Edaravone is a synthetic free radical scavenger and has been proved to be one of the most effective neuroprotective pharmaceuticals, as evidenced by being recommended as the only neuroprotective agent by the Japan Stroke Therapeutic Guide (2004). Edaravone protects the brain by eliminating excessive free radicals, which are highly reactive molecules occurring in the human body as a result of stroke, an excessive number of which could result in cell damage. Bicun was the first edaravone injection approved for sale in China and has been one of our major products since its introduction in China in February 2004. We obtained regulatory approval to manufacture and sell Bicun in December 2003. The monitoring period of Bicun expired in 2007 and a number of competitors have been entered into the edaravone injection market. In 2012, revenues of Bicun amounted to RMB612.2 million (\$98.3 million), which accounted for 29.4% of our revenues for the year.

Table of Contents

**Zailin.** Zailin is the brand name for our line of generic prescription amoxicillin antibiotics, which includes capsules, dispersible tablets, granules and injection. Zailin was recognized as a China Well-Known Trademark by the PRC Trademark Office of the State Administration for Industry and Commerce in 2004 and is one of only two antibiotic brands in China granted such recognition. Regulatory approvals to manufacture and sell Zailin granules were obtained in February 1993, Zailin capsules in October 1996, Zailin tablets in June 1998 and Zailin injection in July 2001. Amoxicillin has been included in the national medical insurance catalog since 2000. In 2012, revenues of Zailin amounted to RMB229.3 million (\$36.8 million), which accounted for 11.0% of our revenues for the year.

**Yingtaiqing.** Yingtaiqing is the brand name for our generic diclofenac sodium in sustained-release capsules and gelatin dosage format, which is an anti-inflammatory pain reliever and analgesic drug used to treat rheumatoid arthritis and osteoarthritis. Yingtaiqing sustained-release capsules are prescription pharmaceuticals and are currently manufactured by a third-party manufacturer, the China Pharmaceutical University Pharmaceutical Company, or China Pharmaceutical, and we have entered into an exclusive distribution agreement with China Pharmaceutical to distribute and sell Yingtaiqing sustained-release capsules in China since 1996. A master distribution agreement was renewed in December 2009. Pursuant to the master distribution agreement, we have agreed to purchase from China Pharmaceutical a certain minimum quantity of Yingtaiqing sustained-release capsules in 2010 and 2011. We obtained the regulatory approval to manufacture and sell Yingtaiqing gelatin, an OTC medicine, in December 2005. Yingtaiqing was recognized as a China Well-Known Trademark in 2008. Diclofenac sodium has been included in the national medical insurance catalog since 2000. In 2012, sales of Yingtaiqing amounted to RMB177.9 million (\$28.6 million), which accounted for 8.5% of our revenues for the year.

**Sinofuan.** Sinofuan is our first-to-market sustained release implants for the treatment of cancer. In April 2008, we acquired Sinofuan by acquiring a 70% equity interest in Simcere Zhong Ren. In 2012, revenues of Sinofuan amounted to RMB159.9 million (\$25.7 million), which accounted for 7.7% of our revenues for the year.

***Other Branded Generic Pharmaceutical Products***

In addition to Endu and our four principal products, the following branded generic pharmaceutical products in aggregate also represented a significant portion of our revenues in 2012 and in aggregate accounted for 19.2% of our revenues in 2012:

- Biqi (smectite powder);
  
- Anqi (amoxicillin with clavulanate potassium granules);
  
- Yidasheng (edaravone injection);
  
- Simcere Kechuaning (herbal medicine used for the treatment of cough in liquids and tablets);

- Jiebaishu (Nedaplatin for Injection); and
- Anxin (Biapenem for Injection).

**Biqi.** Biqi is the brand name for our branded generic anti-diarrhea pharmaceutical. We obtained regulatory approval to manufacture and sell Biqi in November 1999. Biqi has been included in the national medical insurance catalog since 2000.



Table of Contents

**Anqi.** Anqi is the brand name of our amoxicillin and clavulanate potassium tablets, granules, and injection for the treatment of infections. Anqi in tablet and injection form has been included in the national medical insurance catalog since 2000, and Anqi in granule form has been included in the national medical insurance catalog since 2009.

**Yidasheng.** Yidasheng is our prescription edaravone injection pharmaceutical for the treatment of strokes. Yidasheng became our product in October 2007, when we completed the acquisition of a 51.00% equity interest in Jilin Boda, the manufacturer of Yidasheng. In 2010 and 2011, we completed the acquisitions of additional 39.19% and 9.80% of equity interests in Jilin Boda, respectively. Since then, we have held a 99.99% equity interest in Jilin Boda.

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

**Jiebaishu.** Jiebaishu, the first Nelaplatin launched in China in 2003, is primarily used for the treatment of head and neck cancers, small cell lung carcinoma, non-small-cell lung carcinoma, esophageal cancer and other solid tumors.

**Anxin.** Anxin is the brand name of our biapenem for injection, which is for the treatment of severe infections. Anxin has been included in the national medical insurance catalog since 2010.

**Marketing and Distribution**

We have over a decade of marketing experience in the pharmaceutical industry in China. From our inception in March 1995 to 2001, we operated as a distributor of pharmaceuticals and have leveraged our experience to establish an extensive distribution network in China that we now use to market, sell and distribute our own pharmaceuticals. As of December 31, 2012, we had 2,042 dedicated brand management and marketing employees. Our marketing and distribution activities are primarily carried out by our subsidiary, Jiangsu Simcere.

***Our Marketing Strategy***

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

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

We have implemented marketing initiatives designed to promote awareness of our brands among potential customers. In 2008, our brand Yingtaiqing was recognized as a China Well-Known Trademark. In 2009, we further increased brand recognition of Yingtaiqing by sponsoring the Table Tennis Super League events between March and September and by entering into a cooperation agreement with the National Basketball Association, or NBA, in October. From September 2009 to September 2011, under the cooperation agreement with the NBA, we continued to promote brand awareness of Yingtaiqing through various media channels, including television and print. Through these and other brand promotion efforts, such as TV advertising channels, we have solidified and enhanced the market penetration of our Yingtaiqing brand name.

Table of Contents

We started our brand campaign for Biqi in 2006 by placing TV commercials featuring a celebrity couple on China Central Television, or CCTV, China's largest nationwide television network. In 2010, we were the exclusive pharmaceutical sponsor of the film *Aftershock* directed by a well-known Chinese movie director. Brand awareness of Biqi has been elevated through these marketing efforts. In 2011, our branded generic anti-diarrheal pharmaceutical Biqi passed the EU-GMP inspection and received EU-GMP certification from the Finnish Medicines Agency, which demonstrated a higher quality achieved by Biqi. In 2011, we continued to place more TV advertising to enhance the brand image of Biqi.

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

***Distribution***

We sell all of our products (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. Each pharmaceutical distributor in turn may distribute our pharmaceuticals within a designated region either directly to hospitals owned and controlled by counties or higher level government authorities in China, clinics, pharmacies and other retail outlets or to local distributors. Many of our pharmaceuticals are widely distributed in large hospitals located in some of the most prosperous regions in China. Our vaccines are sold to various levels of CDCs, which are controlled by various levels of government authorities in China. 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.

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

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

Table of Contents**Manufacturing, Quality Control and Supplies**

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

A portion of our production lines are equipped with automated machinery and equipment and can be used to produce different kinds of pharmaceuticals in the same physical dosage form without the need to significantly modify the current production facilities and equipment. We therefore are able to adjust our production to meet market demand and our sales target in response to market demand. The following table is a summary of our 2012 production capacity.

<b>Pharmaceutical Agent</b>		
<b>Production Unit</b>	<b>Delivery Form</b>	<b>2012 Capacity</b>
<b>Hainan Simcere</b>		
Penicillin family	Granules	630,000,000 packs
Penicillin family	Capsules	288,000,000 pills
Cefaclor family	Granules	240,000,000 packs
Cefaclor family	Capsules	60,000,000 pills
Cefaclor family	Dry suspension	240,000,000 packs
General	Tablets	200,000,000 pills
General	Granules	240,000,000 packs
General	Gelatin	6,000,000 tubes
General	Powder	160,000,000 packs
General	Capsules	60,000,000 pills
<b>Nanjing Simcere</b>		
Penicillin family	Powder injection	6,600,000 vials
Penicillin family	Granules	40,000,000 packs
Penicillin family	Tablets	70,000,000 pills
General	Oral solution	50,000,000 bottles
	Small volume parenteral solutions	26,000,000 vials
General	Tablets	48,000,000 pills
General	Dry suspension	40,000,000 packs
General	Capsules	38,000,000 capsules
General	Granules	29,000,000 packs
General	Powder injection	2,700,000 vials
General	Sterile active pharmaceutical ingredients, or APIs	1000 kgs
	Extract liquid	21,000,000 vials
Anti-cancer Powder for Injection	Freeze-dried powder injection	3,000,000 bottles
<b>Shandong Simcere</b>		
Recombinant human endostatin	Injection	1,000,000 vials
<b>Jilin Boda</b>		
Edavarone injection	Low-dose injection	20,000,000 vials
General	Tablets	3,000,000,000 pills
General	Capsules	50,000,000 pills
General	Granules	10,000,000 packs
APIs	Moroxydine	900,000 kg
APIs	Edaravone	4,000 kg
<b>Simcere Zhong Ren</b>		

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Fluorouracil implant	Implant	1,000,000 vials
<b>Jiangsu Quanyi</b>		
H1N1 Influenza A Vaccine (Split Virion), Inactivated	Injection	For 6,000,000 people
Influenza Vaccine (Split Virion), Inactivated	Injection	

Table of Contents

***Quality Control***

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

***Raw Materials***

The principal raw materials used for our medical products are the necessary active ingredients of our pharmaceuticals. We source such raw materials, as well as packaging materials, from various independent suppliers in China. In addition, we produce certain active ingredients used for the production of some of our pharmaceutical products, such as Bicun, and we also own the mining rights relating to a smectite mine that produces smectite, a raw material used for the manufacturing of Biqi. In the case of sourcing raw materials from third parties, the purchase price for the relevant raw materials is based on the prevailing market price for such materials of similar quality. Our principal packaging materials include glass ampules for injection pharmaceuticals, plastic bottles for capsule and tablet pharmaceuticals, and external packaging and printed instructions for all of our pharmaceuticals. The principal raw materials used for our vaccine products are egg embryos, which were supplied by two domestic manufacturers.

In 2012, we purchased an aggregate of 31.5% of our total supply of raw materials and pharmaceutical products from our five largest suppliers.

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

**Competition**

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

Our generic pharmaceuticals are not protected by patents and are thus subject to competition from other generic pharmaceuticals. However, the CFDA may at its discretion, subject to certain limitations, grant first-to-market generic pharmaceuticals the protection of a multiple-year monitoring period, or a protection period under the prior regulation, during which other pharmaceutical companies cannot apply for the

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

Table of Contents

The pharmaceutical industry is characterized by rapid product development and technological change. Our pharmaceuticals could be rendered obsolete or made uneconomical by the development of new pharmaceuticals to treat the conditions addressed by our pharmaceuticals, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors. Our business, results of operations and financial condition could be materially adversely affected by any one or more of these developments. Our competitors may also be able to obtain regulatory approval for new products more quickly than we are and, therefore, may begin to market their products in advance of our products. We believe that competition among pharmaceuticals in China will continue to be based on, among other things, brand name recognition, product efficacy, safety, reliability, availability, promotional activities and price.

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

**Environmental Matters**

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



Table of Contents

**Insurance**

We maintain property insurance policies covering our equipment and facilities for losses due to fire, flood and a wide range of other natural disasters. Insurance coverage for our fixed assets other than land amounted to approximately RMB1,205.0 million (\$193.4 million) as of March 31, 2013. We also maintain insurance policies covering products in transit to our customers. 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 addition, we do not maintain business interruption insurance or key employee insurance for our executive officers as we believe it is not the normal industry practice in China to maintain such insurance. We consider our current insurance coverage to be adequate. However, uninsured damage to any of our manufacturing facilities and buildings or a significant product liability claim could have a material adverse effect on our results of operations. We also maintain directors and officers liability insurance for our directors and officers.

**Regulations on Pharmaceutical Products**

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

***Pharmaceutical Product Manufacturing***

*Permits and Licenses for Pharmaceutical Manufacturers*

A manufacturer of pharmaceutical products must obtain a pharmaceutical manufacturing permit from the provincial food and drug administration. This permit, once obtained, is valid for five years and is renewable upon its expiration. This permit must be renewed at least six months before its expiration date. Our current pharmaceutical manufacturing permits for each of Hainan Simcere, Nanjing Simcere Dongyuan, Jiangsu Vaxtec, Shandong Simcere, Jilin Boda and Simcere Zhong Ren will all expire on December 31, 2015. In addition, before commencing business, a pharmaceutical manufacturer must also obtain a business license from the relevant administration for industry and commerce.

*Good Manufacturing Practices*

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

months before its expiration date. A manufacturer is required to obtain GMP certificates to cover all of its production operations.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

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

Certification By Facilities	Coverage	Issue Date	Expiration Date
<b>Hainan Simcere</b>			
	Tablets (Including Cephalosporins), Granules, Capsules, Dry Suspensions (Including Cephalosporins, Penicillin), Soft Capsules, Powders, Gelatin	July 8, 2011	December 31, 2015
	Bulk Drug (Montmorillonite, Igratimod aldioxa)	September 26, 2011	September 25, 2016
	Bulk Drug (Meloxicam, Edaravone)	November 26, 2008	November 25, 2013
	Bulk Drug (Naftopidil, amlodipine maleate)	February 2, 2009	February 1, 2014
	Diosmectite	March 29, 2010	January 27, 2013
	BiQi powder for oral suspension	August 16, 2011	April 10, 2014
<b>Nanjing Simcere</b>			
	Small Volume Parenteral Solutions	December 3, 2008	December 2, 2013
	Mixture, Oral Solution	October 27, 2008	October 26, 2013
	Powder for Injection	August 6, 2008	August 5, 2013
	Sterile Bulk (Biapenem)	July 21, 2008	July 20, 2013
	Tablets, Hard Capsules, Granules, Dry Suspensions, Bulk drug (Palonosetron Hydrochloride)	October 11, 2010	October 10, 2015
	Powder for Injection (Penicillin)	December 28, 2010	December 27, 2015
	Tablets, Capsules, Dry Suspensions (Penicillin)	May 6, 2008	May 5, 2013
	Bulk Drug (Zanamivir), Powder	April 9, 2010	April 8, 2015
	Freeze-dried Powder Injection (Anti-Cancer Drug)	June 16, 2009	June 15, 2014
	Bulk Drug (Nedaplatin)	June 19, 2009	June 18, 2014
	Bulk Drug (Oxaliplatin)	December 28, 2009	December 27, 2014
<b>Shandong Simcere</b>			
	Recombinant Human Endostatin Injection (Anti-cancer Drugs)	August 18, 2009	August 17, 2014
<b>Simcere Zhong Ren</b>			
	Anti-cancer Implants	April 7, 2013	April 6, 2018
<b>Jilin Boda</b>			
	Small Volume Parenteral Solutions, Edaravone Injection	March 14, 2013	March 13, 2018
	Bulk Drug (Edaravone, Phenytoinum Natricum, Moroxydine Hydrochloride)	May 18, 2010	May 17, 2015
	Tablets, Capsules, Granules	November 28, 2008	November 27, 2013
<b>Jiangsu Vaxtec</b>			
	Influenza vaccine	March 14, 2013	March 13, 2018

At the time we acquired Jiangsu Quanyi, its core products included an influenza vaccine and a human-use rabies vaccine (vero cell). Jiangsu Quanyi had also received a new medicine certificate from the CFDA for its freeze-dried human rabies vaccine (vero cell) and had completed clinical trials of its purified hepatitis A inactivated vaccine (vero cell) while CFDA approval for its purified hepatitis A inactivated vaccine (vero cell) and GMP certification for the associated new manufacturing facility were pending. However, as of the date of this annual report, the two new medicine certificates held by Jiangsu Quanyi for its rabies vaccine (vero cell) and freeze-dried human rabies vaccine (vero cell) have been revoked. The 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. Jiangsu Quanyi transferred the vaccine business to Jiangsu Vaxtec, and Jiangsu Vaxtec received the GMP certification of influenza vaccine on March 14, 2013.

*Approval and Registration of Pharmaceutical Products*

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

Table of Contents

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

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

Upon granting production approval of a new medicine, the CFDA may set a monitoring period of a maximum of five years to continue monitoring the safety of the medicine, during which the relevant pharmaceutical manufacturing company must regularly review the production technologies employed, monitor the quality, stability, curative effects and unfavorable side-effects of the new medicine, and report to the provincial level food and drug administration authority annually. During such a monitoring period, the CFDA will not accept applications for new medicine certificates for the same medicine by other pharmaceutical companies or approve the sale or import of the same medicine by other pharmaceutical companies, except that, for any other application for the same new medicine that had been approved by the CFDA to undergo clinical trials prior to the granting of a monitoring period, the CFDA may approve the application for sale or import of the new medicine if it meets the relevant requirements and will continue to monitor such new medicine. As a result, the monitoring period in connection with a new medicine can limit the competition encountered by the manufacturer of the new medicine. On February 10, 2010, the CFDA authorized our company to produce and sell Zanamivir, one of only two drugs approved by the World Health Organization, or WHO, to which the new H1N1 strain of influenza A has been shown to be susceptible. On July 15, 2010, Nanjing Simcere received CFDA new drug certification and registration approval to manufacture and market Palonosetron material and injections in China. Palonosetron is a second generation 5-HT3 antagonist used for the prevention and control of acute chemotherapy-induced nausea and vomiting (CINV). As of March 31, 2013, we held 51 new medicine certificates and had obtained 189 medicine approval documents.

Table of Contents

***Pre-clinical Research and Clinical Trials***

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

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

- Phase I preliminary trial of clinical pharmacology and human safety evaluation studies. The primary objective is to observe the pharmacokinetics and the tolerance level of the human body to the new medicine as a basis for ascertaining the appropriate methods of dosage.
  
- Phase II preliminary exploration on the therapeutic efficacy. The purpose is to assess preliminarily the efficacy and safety of pharmaceutical products on patients within the target indication of the pharmaceutical products and to provide the basis for the design and dosage tests for Phase III. The design and methodology of research in this phase generally adopts double-blind and random methods with limited sample sizes.
  
- Phase III confirm the therapeutic efficacy. The objective is to further verify the efficacy and safety of pharmaceutical products on patients within the target indication of the pharmaceutical products, to evaluate the benefits and risks and finally to provide sufficient experimental proven evidence to support the registration application of the pharmaceutical products. In general, the trial should adopt double-blind, random methods with sufficient sample sizes.
  
- Phase IV stage of application with research conducted by the applicants themselves after the launch of a new pharmaceutical. The objective is to observe the efficacy and adverse reaction of pharmaceutical products under extensive use, to perform an evaluation of the benefits and risks of the application among ordinary or special group of patients, and to ascertain and improve the appropriate dosage volume for application.

***Continuing CFDA Regulation***

A manufacturer of pharmaceutical products is subject to continuing regulation by the CFDA. If an approved medicine, its labeling or its manufacturing process is significantly modified, pre-market supplemental approval may be required. A manufacturer of pharmaceutical products is subject to periodic re-inspection and market surveillance by the CFDA to determine compliance with regulatory requirements. If the CFDA

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

sees a reason to enforce its regulations and rules, the agency can institute a wide variety of enforcement actions such as fines and injunctions, recalls or seizure of products, imposition of operating restrictions, partial suspension or complete shutdown of production and criminal prosecution.

Table of Contents

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

***Regulations on Vaccine Products***

*Classification of Vaccine*

According to the Regulation on the Administration of Circulation and Vaccination of Vaccines, vaccines are classified into two categories based on severity of the disease. Rules and policies regarding the manufacturing, distribution, pricing and quality control of vaccines vary from type to type. Category I vaccines refer to the vaccines provided to the citizens at the expense of the government, which includes the vaccines prescribed in the National Immunization Program and other vaccines designated by provincial government in the execution of the National Immunization Program and vaccines used for emergency or group vaccination executed by the local governments or bureaus of health. Category II vaccines refer to the vaccines to be used in the discretion of a citizen and at his or own expense. We currently do not and do not anticipate in the foreseeable future to manufacture Category I vaccines.

*Quality of Vaccine Products*

On July 13, 2004, the CFDA promulgated the Administrative Regulations for Batch Certificate of Biological Products, which requires competent authority to conduct mandatory inspection and examination on each batch of vaccine products, blood products and other biological products determined by the CFDA before they may be sold in the market. Vaccine products cannot be distributed in the market before they are approved for sale by the relevant medicine inspection institute. An applicant shall apply for examination or inspection, or both examination and inspection, of each batch of vaccine products by the relevant inspection institute. For each batch of vaccine products, the applicant will provide the inspection institute with samples together with manufacturing records, internal inspection records and other quality control documents. The inspection institute will review the documents and inspect the samples and issue a batch certificate within approximately two months, if the manufacture procedures and the quality of the products are ascertained to meet the standards as approved by the CFDA. With the batch certificate, the approved batch of vaccines may be distributed in the market. Copies of batch certificates stamped by the pharmaceutical manufacturing enterprise shall be provided when selling the products.

On June 30, 2005, the CFDA promulgated a circular which reemphasized that rabies vaccine for human-use produced as from August 23, 2005 shall be regulated under the batch certificate system. The National Institute for the Control of Pharmaceutical and Biological Products was authorized by the CFDA to conduct the inspections and issue batch certificates.

*Pricing Policy*



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

According to a circular of the National Development and Reform Commission, or the NDRC, the Printing and Issuing of the Price Controlled List of Drugs promulgated on June 27, 2005 that took effect on August 1, 2005, the prices of Category I vaccines are subject to the control of the NDRC. Specifically, on July 28, 2009, the NDRC promulgated a circular on the manufacturers' prices of fourteen National Immunization Program vaccines, in which the NDRC fixed the respective price ceilings of the fourteen vaccines. For those drugs not covered in the Price Control List, which are the Category II vaccines, distributors and manufacturers are entitled to set the prices. None of our current products is a Category I vaccine and we are not currently subject to price controls imposed by the NDRC. However, we cannot assure you that the NDRC will not revise its rules and include certain or all of our current products in Category I in the future.

Table of Contents

*Other National and Local Laws and Regulations*

We are subject to changing regulations under many other laws administered by governmental authorities at the national, provincial and municipal levels in China. Our CDC customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

For example, we need to comply with numerous national and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control. We believe that we are currently in compliance with these laws and regulations. However, unanticipated changes in existing regulatory requirements or adoption of new requirements could cause us to incur significant costs to comply and therefore have a material adverse effect on our business, results of operations and financial condition.

***Distribution***

*Pharmaceutical Distribution*

A distributor of pharmaceutical products must obtain a pharmaceutical distribution permit from the relevant provincial- or designated municipal- or county-level food and drug administration. The grant of such permit is subject to an inspection of the distributor's facilities, warehouse, hygiene environment, quality control systems, personnel and equipment. The pharmaceutical distribution permit is valid for five years. In addition, a pharmaceutical distributor needs to obtain a business license from the relevant administration for industry and commerce prior to commencing its business.

*Vaccine Distribution*

The eligibility of the distributors and channels of vaccines depend on the type of vaccines being distributed. As to Category I vaccines, provincial CDCs compose annual provincial vaccination programs of Category I vaccines and report to the provincial Bureau of Health and other competent authorities in charge of vaccine trading. Vaccine manufacturing enterprises and qualified vaccine wholesalers are required to enter into exclusive purchase contract with the competent provincial CDCs or other disease control and prevention organizations for the distribution of Category I vaccine. The vaccine manufacturers may only sell Category I vaccines to provincial CDCs. The provincial CDCs are accountable for distributing Category I vaccines to the municipal and local CDCs, which are obligated to distribute Category I vaccine to lower CDCs.

A pharmaceutical manufacturing enterprise may sell Category II vaccines it produces to CDCs at various levels, vaccine inoculation organizations and qualified vaccine wholesalers. Qualified vaccine wholesalers are entitled to sell vaccines to CDCs, vaccine inoculation organization and other qualified vaccine wholesalers, whereas pharmaceutical retailers are banned from engaging in vaccine trading. The pharmaceutical manufacturing enterprises are required to provide copies of batch certificate or permit issued by a competent pharmaceutical authority with its company stamp when trading vaccines. The pharmaceutical manufacturing enterprises are also required to keep the records of sales of vaccines for a minimum period of two years after the expiration date of vaccines. Penalties may be imposed on the pharmaceutical

manufacturing enterprise if it fails to comply with these requirements.

Table of Contents

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

The Administration Rules on Foreign Investment in Commercial Domains and the Catalogue of Industries for Guiding Foreign Investment permit foreign companies to establish or invest in wholly foreign-owned companies or joint ventures that engage in wholesale or retail sales of pharmaceuticals in China. In relation to retail sales, the number and size of retail pharmacy outlets that a foreign investor may establish remain subject to certain restrictions. Pharmacy chains with more than 30 outlets and selling a variety of branded pharmaceutical products sourced from different suppliers are limited to less than 50.0% foreign ownership. However, under the Supplement Regulations for Administration Rules on Foreign Investment in Commercial Domains, a service provider from Hong Kong or Macau may provide up to 100% of the capital contributions to such pharmacy chains that it opens.

*Good Supply Practices*

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

Our subsidiary, Jiangsu Simcere, obtained its most recent GSP certificates on July 2, 2008. The certificate is valid for five years and we do not believe it would be difficult for us to renew this certificate.

*Product Liability and Consumer Protection*

In addition to the new drug approval process, certain PRC laws have been promulgated to protect the rights of all consumers including consumers of pharmaceutical products. Pursuant to the PRC General Principles of the Civil Law, or the PRC Civil Law, promulgated on April 12, 1986, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

On February 22, 1993 the PRC Product Quality Law, or the Product Quality Law, was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was revised by the Ninth National People's Congress on July 8, 2000. Pursuant to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and their business licenses may be revoked.

On October 31, 1993, the PRC Law on the Protection of the Rights and Interests of Consumers, or the Consumers Protection Law, was promulgated. It provides further protection to the legal rights and interests of consumers in connection with the purchase or use of goods and services. Pursuant to the Consumers Protection Law, a consumers' association was established to handle consumer complaints and assist consumers. The Consumers Protection Law also detailed the compensation consumers and certain third parties are entitled to when property damage or physical injury is incurred.

The PRC Tort Liability Law, or the Tort Liability Law, was promulgated on December 26, 2009 and took effect on July 1, 2010. The Tort Liability Law provides that once a product is found defective after it is put into circulation, the product manufacturer or seller shall timely take remedial actions such as warning or products recall. If the failure to timely take sufficient remedial action results in harm or damage, the product manufacturer or seller will assume tort liability.

Table of Contents

***Price Controls***

The retail prices of certain pharmaceuticals sold in China, primarily those included in the Drug List and Reimbursement List and those pharmaceuticals whose production or trading are deemed to constitute monopolies, are subject to price controls in the form of fixed prices or price ceilings. Manufacturers and distributors cannot set the actual retail price for any given price-controlled product above the price ceiling or deviate from the fixed price imposed by the government. The prices of medicines that are not subject to price controls are determined freely at the discretion of the respective pharmaceutical companies, subject to register to the provincial pricing authorities. Sales of pharmaceutical products by pharmaceutical manufacturers in China to overseas markets are not subject to any price control.

The retail prices of medicines that are subject to price controls are administered by the Price Control Office of the National Development and Reform Commission, or the NDRC, and provincial and regional price control authorities. The retail price, once set, also effectively determines the wholesale price of that medicine. From time to time, the NDRC publishes and updates a list of medicines that are subject to price controls. Fixed prices and price ceilings on medicines are determined based on profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, its production costs, the prices of substitute medicines and the extent of the manufacturer's compliance with the applicable GMP standards. The NDRC directly regulates the price of all medicines on the Reimbursement list, and delegates to provincial or regional authorities the authority to regulate the pricing of the rest of the medicines that are not included in the reimbursement list. Provincial and regional price control authorities have discretion to authorize price adjustments based on the local conditions and the level of local economic development.

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

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

***Tendering System for Medicines Purchased by Healthcare Institutions***

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



Table of Contents

***Reimbursement Under the National Medical Insurance Program***

Participants of National Medical Insurance Program are urban residents who are currently employed or retired. Participants of the National Medical Insurance Program and their employers are required to contribute to the payment of insurance premium on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the Essential Drug List and Reimbursement List, which is divided into two tiers. Purchases of Tier A medicines are fully reimbursable, but certain Tier A medicines are only reimbursable if the medicine is used for a particular stated purpose in the Essential Drug List and Reimbursement List. Purchasers of Tier B medicines are required to make a certain percentage of co-payments, with the remaining amount being reimbursable. The percentage of reimbursement for Tier B medicines varies in different regions in the PRC. Factors that affect the inclusion of medicines in the Essential Drug List and Reimbursement List include whether the medicine is consumed in large volumes and commonly prescribed for clinical use in China and whether it is considered to be important in meeting the basic healthcare needs of the general public. The Ministry of Human Resources, together with other government authorities, has the power every four years to determine which medicines are included in the national medicine catalog, under which of the two tiers the included medicine falls, and whether an included medicine should be removed from the catalog. Provincial governments are required to include all Tier A medicines listed on the national medical insurance catalog in their provincial Essential Drug List and Reimbursement List. For Tier B medicines listed in the national medical insurance catalog, provincial governments have the discretion to include or remove by no more than 15% from the number of Tier B medicines listed in the national medical insurance catalog that is to be included in the provincial Essential Drug List and Reimbursement List. The patients under the Reimbursement program can be reimbursed for certain hospitalization costs on an annual basis; and if they go to the clinic for medical treatment or purchase medicines in drugstores, they cannot be reimbursed.

***PRC Patent Law***

The PRC first allowed patents for the protection of proprietary rights, as set forth in the PRC Patent Law, in 1985. Pharmaceutical inventions were not patentable under the PRC Patent Law until 1993. Patents relating to pharmaceutical inventions are effective for 20 years from the initial date the patent application was filed. An amendment to the PRC Patent Law was promulgated on December 27, 2008, with the amendment becoming effective on October 1, 2009. The Implementing Regulations of the PRC Patent Law was promulgated on December 30, 2009 and came into effect on February 1, 2010.

***Patent Prosecution***

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





Table of Contents

*Patent Enforcement*

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

*Compulsory License*

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

*International Patent Treaties*

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

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

*PRC Trademark Law*

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

Table of Contents

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

- use of a trademark that is identical with or similar to a registered trademark in respect of the same or similar commodities without the authorization of the trademark registrant;
- sale of commodities infringing upon the exclusive right to use the trademark;
- counterfeiting or making, without authorization, representations of a registered trademark of another person, or sale of such representations of a registered trademark;
- changing a registered trademark and selling products on which the changed registered trademark is used without the consent of the trademark registrant; and
- otherwise infringing upon the exclusive right of another person to use a registered trademark.

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

- The trademark owner can provide his trademark registration certificate and other relevant evidence to the State or local Administration for Industry and Commerce, or AIC, which can, at its discretion, launch an investigation. The AIC may take such actions as: order the infringer to immediately cease the infringing behavior, seize and destroy any infringing products and representations of the trademark in question, close the facilities used to manufacture the infringing products or impose a fine. If the trademark owner is dissatisfied with the State AIC's decision, he may, within 15 days of receiving the AIC's decision, institute civil proceedings in court.
- The trademark owner may institute civil proceedings directly in court. Civil redress for trademark infringement includes:
  - injunctions;
  - requiring the infringer to take steps to mitigate the damage (i.e. print notices in newspapers); and

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

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

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

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

Table of Contents

***Foreign Exchange Regulation***

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

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

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

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

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

***Dividend Distribution Regulation***

The principal laws and regulations governing dividends paid by our PRC operating subsidiaries include the Company Law of the People's Republic of China (1993), amended and effective as of January 1, 2006, Wholly Foreign Owned Enterprise Law (1986), as amended in 2000, and Wholly Foreign Owned Enterprise Law Implementation Rules (1990), as amended in 2001. Under these laws and regulations, each of our PRC subsidiaries, including WFOEs and domestic companies in China may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, each of our PRC subsidiaries, including WFOEs and domestic companies is required to set aside at least 10.0% of its after-tax profit based on PRC accounting standards each year to its general reserves or statutory capital reserve fund until the accumulative amount of such reserve reaches 50.0% of its respective registered capital. These

reserves are not distributable as cash dividends.

Table of Contents

C. *Organizational Structure*

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



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

We conduct substantially all of our operations through the following operating subsidiaries.

- Simcere Pharmaceutical Co., Ltd., or Hainan Simcere, is our wholly owned subsidiary that engages in the manufacturing of pharmaceutical products. Hainan Simcere is currently authorized to manufacture 63 pharmaceutical products.
- Nanjing Simcere Dongyuan Pharmaceutical Co., Ltd., or Nanjing Simcere, is our wholly owned subsidiary that engages in the manufacturing of pharmaceutical products. Nanjing Simcere is currently authorized to manufacture 87 pharmaceutical products.
- Jiangsu Simcere Pharmaceutical Co., Ltd., or Jiangsu Simcere, is our wholly owned subsidiary that engages in the marketing, sale and distribution of pharmaceutical products.
- Sichuan Zigong Yirong Industrial Co., Ltd., or Sichuan Simcere, is our wholly owned subsidiary that owns the mining right to a smectite mine in Sichuan Province and engages in the extraction of smectite, a raw material used for the manufacturing of one of our pharmaceutical products.
- Hainan Qitian Pharmaceutical Co., Ltd., or Qitian Simcere, is our wholly owned subsidiary that engages in the processing and refinement of smectite.
- Shandong Simcere Medgenn Bio-Pharmaceutical Co., Ltd., or Shandong Simcere, formerly known as Yantai Medgenn Co., Ltd., is our wholly owned subsidiary that engages in the manufacturing of Endu in China. We completed the acquisition of 80.0% of the equity interest of Shandong Simcere in September 2006 and an additional 10.0% of the equity interest in Shandong Simcere in June 2007. In January 2009, we acquired the remaining 10.0% of the equity interest in Shandong Simcere, which is now our wholly owned subsidiary. In addition, Shandong Simcere owns a 40.0% equity interest in Medgenn (Hong Kong) Co., Ltd., or Hong Kong Medgenn, which was acquired for no cash consideration. Hong Kong Medgenn has the exclusive right to engage in the development and sale of Endu in any jurisdiction outside of the PRC until February 10, 2015. Hong Kong Medgenn has not conducted any operations to date.
- Jilin Boda Pharmaceutical Co., Ltd., or Jilin Boda, is our 99.99% owned subsidiary that engages in the manufacturing and sale of pharmaceutical products. Prior to July 2010, we owned 51.0% of the equity interest in Jilin Boda. In 2010 and 2011, we acquired approximately 39.19% and 9.80% of the equity interests in Jilin Boda, respectively.
- Wuhu Simcere Zhong Ren Pharmaceutical Co., Ltd., or Simcere Zhong Ren, is our 70.0% owned subsidiary that engages in the manufacturing and sale of pharmaceutical products. We completed the acquisition of the 70.0% equity interest in Simcere Zhong Ren in April 2008.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- Jiangsu Quanyi Biological Technology Stock Co., Ltd., or Jiangsu Quanyi, engaged in the manufacturing and sale of vaccines. In May 2009, we acquired a 37.5% equity interest in Jiangsu Quanyi. In December 2009, we acquired the 100.0% equity interest in China Vax, a Cayman Islands investment holding company which held a 15.0% equity interest in Jiangsu Quanyi. Since then, we have held 52.5% of the equity interest in Jiangsu Quanyi.
- Jiangsu Simcere Vaxtec Bio-Pharmaceutical Co., Ltd., or Jiangsu Vaxtec, a subsidiary in which we holds a 52.5% equity interest that engages in the manufacturing and sale of vaccines.
- Simcere of America Inc. or Simcere America is our wholly owned subsidisary that engages in searching for cooperation opportunity outside China.
- Beijing Simcere Pharmaceutical Investment Co., Ltd., Beijing Xiangao Bio-Tech Co., Ltd., Beijing Xianjun Info-Tech Co., Ltd., and Oy Simcere Europe Limited are our wholly owned subsidiaries established in 2011 with no substantial business operations.
- Right Wealth Holdings Limited, Cosmo Key Limited, Nanjing Simcere Dongyuan Technology & Trade Co., Ltd. are our wholly owned subsidiaries established in 2012.

### *D. Property, Plants and Equipment*

Our headquarters and our research and development facility are located in Nanjing, Jiangsu Province, on a parcel of land with an aggregate site area of approximately 193,100 square meters. The land use rights will expire in 2056. In 2012, we cancelled the framework agreement with Beijing Strong Science Park Development Co., Ltd that was entered into in March 2011 for the planned purchase of land-use rights to establish a regional research and development center and offices, and withdrew the deposit payments of RMB 19.4 million (\$3.1 million). In June 2011, we entered into an agreement with Chenmai government in Hainan Province to purchase land use rights with respect to an aggregate site area of approximately 260,000 square meters. Deposits payments of RMB33.0 million (\$5.3 million) were made in 2011.

Table of Contents

We have six GMP-approved manufacturing facilities that are located in Nanjing and Changzhou in Jiangsu Province, Haikou in Hainan Province, Liaoyuan in Jilin Province, Yantai in Shandong Province, Wuhu in Anhui Province. Our facilities in Nanjing are approximately 36,677 square meters in total, occupying four parcels of land with an aggregate site area of approximately 309,788 square meters. The land use rights granted with respect to the lands will expire in 2048, 2054 and 2054 and 2056. Our facility in Haikou, Hainan Province is approximately 17,000 square meters and occupies a parcel of land with an aggregate site area of approximately 40,000 square meters. The land use rights will expire in 2067. The facility in Yantai, Shandong Province is approximately 3,000 square meters and occupies a parcel of land with an aggregate site area of approximately 48,000 square meters. The land use rights will expire in 2053. The facility in Liaoyuan, Jilin Province is approximately 19,827 square meters and occupies an aggregate site area of approximately 55,000 square meters. The land use rights will expire in 2056. The facility in Wuhu, Anhui Province is approximately 3,143 square meters and occupies a parcel of land with an aggregate site area of approximately 20,000 square meters. The land use rights will expire in 2052. The facility in Changzhou, Jiangsu Province is approximately 41,444 square meters and occupies a parcel of land with an aggregate site area of approximately 50,429 square meters. The land use rights will expire in 2056. In addition, we own the mineral exploration rights relating to a smectite mine that can produce 300,000 tons in total of smectite, a raw material used for the manufacturing of our diarrhea medicine Biqi.

We believe that our existing facilities, together with the facilities under construction, are adequate for our current requirements.

In addition, in accordance with recent local government policies, we will be required to relocate two of our subsidiaries to the suburban areas. We are currently formulating the relocation plan and, therefore, we are unable to ascertain the financial impact these relocations may have on our results of operations and financial condition.

**Item 4A. UNRESOLVED STAFF COMMENTS**

None.

**Item 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

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

**A. Operating Results**

**Overview**

We are a leading manufacturer and supplier of branded generic pharmaceuticals in the fast growing China market. We focus our strategy on the development of first-to-market generic and innovative pharmaceuticals. We currently manufacture and sell 47 principal pharmaceutical products and are the exclusive distributor of two additional pharmaceutical products that are marketed under our brand names. We market and sell our products directly or indirectly to approximately 1,405 pharmaceutical distributors who in turn sell these products to other distributors, hospitals and retail pharmacies throughout China.

Table of Contents

We commenced operations in March 1995 and operated our business mainly as a distributor of pharmaceutical products. Since then, we have gradually built up our research and development and manufacturing capabilities and have become one of the leading pharmaceutical companies in China that develop, manufacture and sell branded generic pharmaceuticals. To date, we have introduced a series of branded products, including our first-to-market generic anti-stroke medication Bicun, as well as our innovative pharmaceutical Endu, the first recombinant human endostatin injection approved for sale in China. Revenues from Bicun, Zailin, Yingtaiqing, Endu and Sinofuan, on an individual basis, exceeded RMB100.0 million (\$16.1 million) in 2012, which we believe is evidence of wide market acceptance of these products in the China market.

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

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

***The Growth of the Pharmaceutical Market in China***

With approximately one-fifth of the world's population and a fast-growing gross domestic product, China represents a significant potential market for the pharmaceutical industry. We believe the pharmaceutical market in China is expected to grow due to factors such as robust economic growth, increased pharmaceutical expenditure, an aging population, an increase in lifestyle-related diseases, government support of the pharmaceutical industry, the relatively low research and development and clinical trial costs in China as compared to more developed countries, as well as the increased availability of funding for medical insurance and industry consolidation in China. Our business and revenue growth primarily depend on the size and growth of the pharmaceutical products in China. As a result, our revenue and profitability may be negatively affected by changes in national, regional or local economic conditions and consumer confidence in China. In particular, as we focus our expansion of retail stores in metropolitan markets, where living standards and consumer purchasing power are higher than rural areas, we are especially susceptible to changes in economic conditions, consumer confidence and customer preferences of the urban Chinese population. See

Item 3. Key Information D. Risk Factors Risks Related to Our Industry Changes in economic conditions and consumer confidence in China may influence consumer preferences and spending patterns, and accordingly, our results of operations.

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

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

Table of Contents

***The Extent of Inclusion of Our Pharmaceuticals in the Essential Drug List and Reimbursement List***

Eligible participants in the national basic medical insurance program in China, which consist of mostly urban staff and residents, 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 and Provincial Medical Insurance Programs. In August 2009, the PRC Ministry of Health established the essential drug list, which contains 205 chemical drugs and 102 traditional Chinese medicines. On November 30, 2009, China's Ministry of Human Resources and Social Security issued China's national drug reimbursement list consisting of 2,127 Tier A and Tier B drugs. Factors that affect the inclusion of medicines in the Essential Drug List and Reimbursement List include whether the medicine is consumed in large volumes and commonly prescribed for clinical use in China, whether it is considered to be important in meeting the basic healthcare needs of the general public, whether the price is reasonable and whether it is safe and effective. As of March 31, 2013, 36 of our 47 principal products, including Edaravone (Bicun and Yidasheng), Nedaplatin (Jiebaishu), Diclofenac (Yingtaiqing), Amoxicillin (Zailin), Biapenem (Anxin), Amoxicillin and Clavulanate (Anqi), Levamlodipine (Xinta), Alfalcidol (Faneng), Smectite (Biqi), Kechuanning and Rosuvastatin (Shufutan), have been included in the Essential Drug List or Reimbursement List.

The inclusion of a medicine in the Essential Drug List and Reimbursement List can substantially improve the sales volume of the medicine due to the availability of third-party reimbursements. However, pharmaceuticals included in the Essential Drug List and Reimbursement List are subject to price adjustments by the national authorities. Such price controls, especially downward price adjustments, may negatively affect the unit price of our products. See Product Pricing and Price Controls. On balance, we believe that the benefit of the inclusion of our pharmaceuticals in the Essential Drug List and Reimbursement List outweighs the cost of such inclusion.

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

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

A substantial portion of the products we sell to our distributor customers are sold to hospitals owned or controlled by counties or higher level government authorities in China. These hospitals must implement collective tender processes for the purchase of medicines listed in the Essential Drug List and Reimbursement List and consumed in large volumes and commonly prescribed for clinical uses. Factors considered by these hospitals in assessing bids include, among other things, the quality and price of the medicine and the service and reputation of the manufacturers. The collective tender process for pharmaceuticals with the same chemical composition must be conducted annually in principle, and pharmaceuticals that have won in the collective tender processes previously must 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.





Table of Contents

***Product Pricing and Price Controls***

In October 2009, the NDRC implemented pricing ceilings on 2,349 pharmaceutical products, including drugs or medicines which are on the Essential Drug List. Certain of our pharmaceutical products sold in China, primarily those included in the Essential Drug List and Reimbursement List, are subject to price controls in the form of fixed prices or price ceilings. Controls over and adjustments to the retail price of a pharmaceutical may have a corresponding impact on the wholesale price of that pharmaceutical. From time to time, the PRC government publishes and updates a list of medicines that are subject to price controls, either at the national level or the provincial or regional level. Fixed prices and price ceilings on medicines are determined based on profit margins that the relevant government authorities deem reasonable, the type and quality of the medicine, its production costs, the prices of substitute medicines and the extent of the manufacturer's compliance with the applicable GMP standards. See Item 4. Information on the Company B. Business Overview Regulation Price Controls.

As of March 31, 2013, 36 of our 47 principal products, including Edaravone (Bicun and Yidasheng), Nedaplatin (Jiebaishu), Diclofenac (Yingtaiqing), Amoxicillin (Zailin), Biapenem (Anxin), Amoxicillin and Clavulanate (Anqi), Levamlodipine (Xinta), Alfacalcidol (Faneng), Smectite (Biqi), Kechuanning and Rosuvastatin (Shufutan), have been included in the Essential Drug List or Reimbursement List.

Since May 1998, the relevant PRC government authorities have ordered price reductions of various pharmaceuticals 31 times. The latest price reductions occurred in January 2013 and affected a total of 1,188 pharmaceuticals.

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

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

**Acquisitions**

In 2006 and 2007, we acquired an aggregate of 90.0% equity interest in Shandong Simcere, a PRC pharmaceutical company engaged in the research, development, manufacture and sale of an anti-cancer medication under the name Endu. In January 2009, we acquired the remaining 10.0% equity interest in Shandong Simcere for cash consideration of RMB30.1 million.



Table of Contents

In September 2007, we entered into a definitive agreement to acquire a 51.0% equity interest in Jilin Boda for a total of RMB123.1 million in cash. The acquisition was completed in October 2007. Jilin Boda manufactures the injectable stroke management medication, Yidasheng, the only other edaravone injection currently available in China other than Bicun at that time. In June 2010, we entered into a series of transactions to: (i) acquire approximately 39.19% of the equity interest in Jilin Boda through an acquisition of 80.0% equity interest in Nanjing Xiangao, an investment company which holds approximately 48.99% of the equity interest in Jilin Boda; and (ii) acquire the remaining 20.0% of the equity interest in Nanjing Xiangao through a put-and-call arrangement, which would allow us to effectively acquire approximately 9.80% of the equity interest in Jilin Boda. The additional purchase of 39.19% of the equity interests in Jilin Boda did not constitute a change in control. These series of transactions were completed on July 4, 2010 with a total purchase consideration of RMB174.2 million, consisting of cash consideration of RMB170.2 million and RMB4.0 million, representing the difference between RMB30.4 million, the fair value of buildings, machinery and equipment transferred to the selling shareholder, and RMB26.4 million, the consideration receivable from the selling shareholder. In December 2011, we acquired an additional 9.80% equity interest in Jilin Boda through the acquisition of a 20% equity interest in Nanjing Xiangao for cash consideration of RMB40.0 million. As of December 31, 2012, we beneficially held a 99.99% equity interest in Jilin Boda.

In November 2007, we acquired 100.0% of the equity interest in Master Luck Corporation Limited, which in turn holds 85.7% of the equity interest in Nanjing Tung Chit, the manufacturer of nedaplatin injection, a chemotherapy pharmaceutical that is marketed under the brand name Jiebaishu. The total consideration for the acquisition was RMB32.9 million in cash. We believe Jiebaishu, as a leading nedaplatin product in China, further complements our current portfolio of anti-cancer pharmaceuticals that already include our innovative pharmaceutical Endu, as well as provide us with a manufacturing facility and production line for chemotherapy pharmaceuticals that is in compliance with GMP standards. In April 2010, Nanjing Tung Chit became our wholly owned subsidiary after we acquired the remaining 14.3% equity interest for RMB6.3 million in cash. Nanjing Tung Chit merged into Nanjing Simcere Dongyuan in March 2011.

In April 2008, we acquired a 70.0% equity interest in Simcere Zhong Ren, the manufacturer of first-to-market 5-FU sustained release implants for the treatment of cancer under the brand name of Sinofuan, for a total consideration of RMB65.1 million in cash, to enhance our offerings in the anti-drug market and create synergies with Endu, the anti-tumor drug.

In May 2009, we entered into an agreement to indirectly acquire approximately 35.0% of the equity interest of Shanghai Celgen Bio-Pharmaceutical Co., Ltd., or Shanghai Celgen, for cash consideration of RMB110.0 million. Shanghai Celgen has strong expertise in research and production of therapeutic antibodies and possesses an antibody manufacturing facility in Shanghai, for which the medicine certificate was approved by the CFDA in March 2011 and the GMP certification was granted in September 2011. Shanghai Celgen's major biogeneric drug candidate, an etanercept, has completed clinical trials and was approved by the CFDA in April 2011. We commenced the production and sale of etanercept in September 2011. As of December 31, 2012, our management approved a plan to sell the investment in Shanghai Celgen. On January 15, 2013, we entered into a share transfer agreement and agreed to transfer a 35% equity interest in Shanghai Celgen to Devont Asset Management Limited, for consideration of RMB 302.0 million (\$ 48.5 million). Consummation of the transaction is subject to certain closing conditions.

In May 2009, we entered into an agreement to acquire a 37.5% equity interest in Jiangsu Quanyi, a China-based developer and manufacturer of vaccines, for cash consideration of RMB195.5 million. In October and November 2009, we entered into two agreements pursuant to which we acquired 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 total consideration of RMB102.7 million. After completion of this acquisition, we hold an aggregate of 52.5% of the equity interest in Jiangsu Quanyi.

Table of Contents

After we entered into the share purchase agreements in October and November 2009 to acquire a 15.0% equity interest in Jiangsu Quanyi, but prior to the completion of the transaction, we discovered quality control problems relating to the production of Jiangsu Quanyi's human-use rabies vaccine (vero cell). On November 23, 2009, we urged the board of Jiangsu Quanyi to replace its general manager and head of quality assurance and demanded that Jiangsu Quanyi implement a total suspension of production effective on November 30, 2009 to facilitate internal inspection and rectification of its quality control systems.

On December 3, 2009, the 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 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 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.

In August 2011, Jiangsu Quanyi injected certain of its machineries and equipments as paid-in capital into Jiangsu Vaxtec, the wholly-owned subsidiary of Jiangsu Quanyi, which would be used for the production of influenza vaccine. Jiangsu Vaxtec obtained the GMP certification of influenza vaccine and commenced production in March 2013.

**Revenues**

We generate revenues mainly from the sales of our products. Our product revenues represent our revenues from the sales of our products, less value-added taxes, or VAT.

Our products include antibiotics, anti-stroke medications, anti-inflammatory drugs, anti-cancer vaccine and other medicines. We generate a substantial portion of our revenues from sales of Bicun, Zailin, Endu, Yingtaiqing, and Sinofuan, which in aggregate, accounted for 71.9%, 72.2% and 69.6% of our revenues in 2010, 2011 and 2012, respectively.



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

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

	2010		Year Ended December 31, 2011		2012	
	(in thousands of RMB)	(% of revenues)	(in thousands of RMB)	(% of revenues)	(in thousands of RMB)	(% of revenues)
Bicun	667,669	31.2	654,643	32.1	612,236	29.4
Endu	223,090	10.4	263,046	12.9	271,214	13.0
Zailin	320,833	15.0	191,006	9.4	229,303	11.0
Yingtaiqing	175,296	8.2	185,441	9.1	177,884	8.5
Sinofuan	151,829	7.1	178,146	8.7	159,884	7.7

We sell substantially all of our products (except for vaccines) to pharmaceutical distributors as we believe this is the most cost-effective way to reach a broad end-user base. We typically enter into written distribution agreements with our distributor customers for one-year terms that are generally renewed annually. Our sales are generally made on a purchase order basis, rather than under any long-term commitments. We compete for desired distributors with other pharmaceutical manufacturers. Any disruption of our distribution network, including failure to renew existing distribution agreements with desired distributors or establish relationships with important new distributors, could negatively affect our ability to effectively sell our products, which could materially and adversely affect our revenues and profitability. Furthermore, we have limited ability to manage the activities of our distributors as they are independent from us. Our distributors may potentially engage in actions that may violate the anti-corruption laws in China, engage in other illegal practices or damaging behaviors with respect to their sales or marketing of our products, which could have a material adverse effect on our business, prospects and brand.

Our distributor customers are widely dispersed on both a geographic and revenues basis even though each distributor is limited to its respective designated distribution areas as specified in our distribution agreements. In 2010, 2011 and 2012, no single distributor accounted for, on an individual basis, 10.0% or more of our revenues, and sales to our five largest distributors accounted in aggregate for approximately 17.6%, 17.2% and 16.6%, respectively, of our revenues.

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

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

From past experiences, the losses of uncollectible accounts receivable were immaterial. In 2010 and 2011, bad debt expense amounted to RMB0.8 million and RMB1.0 million, respectively. In 2012, reversal of bad debt expense amounted to RMB0.6 million (\$0.1 million). Our allowance for doubtful accounts amounted to RMB7.3 million and RMB6.7 million (\$1.1 million) as of December 31, 2011 and 2012, respectively.



Table of Contents**Cost of Materials and Production and Operating Expenses**

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

	2010	Year Ended December 31, 2011 (in percentages)	2012
Cost of materials and production	16.0	16.1	17.3
Operating expenses			
Research and development expenses	5.9	9.7	11.0
Sales, marketing and distribution expenses	55.4	55.5	54.8
General and administrative expenses	12.6	14.1	12.3
Impairment charges			4.6
Total operating expenses	73.9	79.3	82.7

Our cost of materials and production as a percentage of our revenues was stable from 2010 to 2011. Our cost of materials and production increased as a percentage of our revenues from 2011 to 2012, due primarily to the decrease in sales percentage of drugs with higher gross margin and the price decrease of certain drugs. Our operating expenses increased as a percentage of our revenues from 2010 to 2011 primarily due to the increase in research and development expense as a result of increased expenditures on on-going research and development projects and an increase in the number of research and development personnel. Our operating expenses increased as a percentage of our revenues from 2011 to 2012 mainly due to a write-down of intangible assets, goodwill, and assets held for sale associated with the acquisition of Jiangsu Quanyi in 2009.

***Cost of Materials and Production***

Our cost of materials and production primarily consists of:

- costs of the pharmaceuticals in which we are the exclusive distributors of;
- costs of the necessary active ingredients and supporting ingredients of pharmaceuticals we manufacture and various types of packaging materials;
- salaries and benefits for personnel directly involved in production activities;



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- overhead costs, including utility, maintenance of production equipment and other support expenses associated with the production of our products; and
  
- depreciation of property, plant and equipment used for production purposes. Depreciation of property, plant and equipment attributable to production activities is capitalized as part of inventory, and expensed as cost of materials and production when products are sold.

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

Table of Contents

***Research and Development Expenses***

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

Our research and development expenses primarily consist of costs associated with the research and development of our product candidates. To develop product candidates, we use our in-house expertise as well as collaborate with leading universities and research institutions in China. Expenses associated with our in-house research and development activities include costs of engaging in market analysis to determine the commercial viability of potential pharmaceuticals, costs of employee compensation, costs of clinical pharmaceutical supplies, other supplies and materials, and intellectual property, travel and facilities costs. As to our collaboration arrangements with research institutions in China, we are generally responsible for the provision of funding and research assistance for the joint development of new pharmaceuticals. If the pharmaceuticals are successfully developed and new medicine certificates with respect to such pharmaceuticals are obtained, we will generally hold the rights to commercializing such products and in limited circumstances, will hold the rights to commercializing such products jointly with our research partners.

We are developing a number of new pharmaceuticals through our in-house expertise and through joint research and development efforts with universities and research institutions in China. As of March 31, 2013, we had over 11 product candidates in various stages of development. We plan to commence the manufacturing, marketing and sales of these products as soon as we obtain the relevant CFDA approvals.

The successful development of pharmaceutical products can be affected by many factors. Product candidates that appear to be promising at their early phases of research and development may fail to be commercialized for various reasons, including the failure to obtain the necessary regulatory approvals. In addition, the research and development cycle for innovative pharmaceuticals for which we may obtain an approval certificate is long. The process of conducting basic research and various stages of tests and trials of a new innovative pharmaceutical before obtaining an approval certificate and commercializing the product may require more than ten years. There is no assurance that our research and development projects will produce a commercially viable result. Even if such products can be successfully commercialized, they may not achieve the level of market acceptance that we expect, and our business and profitability could be materially and adversely affected. See Item 3. Key Information D. Risk Factors Our future research and development projects may not be successful. Furthermore, as the research and development cycle for innovative pharmaceuticals is long, our expenditures on current and future research and development projects are subject to many uncertainties. The cost of research and development projects may vary significantly over the life of a research and development project as a result of a variety of factors, including:

- the delay in research and development of certain projects preventing us to focus our resources on more promising product candidates;
- the intended use of a product candidate, which affects the length and timing of the research and development projects;
- the number of patients who participate in the clinical trials;

- the number of sites included in clinical trials;
- the length of time required to enroll clinical trial participants;
- the duration of patient treatment and follow-up during clinical trials;
- the costs of producing supplies of the product candidates needed for clinical trials; and
- the requirement and timing of CFDA approvals.

Table of Contents

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

We expense research and development costs as and when incurred. These expenses include the costs of our internal research and development activities and the costs of research and development conducted by others on our behalf, such as through third-party collaboration arrangements discussed above. Research and development costs in connection with third party research and development collaboration arrangements prior to obtaining regulatory approval are expensed when the research and development activities are performed. Costs incurred to obtain developed technology and costs incurred subsequent to obtaining regulatory approval are capitalized and amortized over the shorter of the remaining license period and the patent protection period for the product.

Our IPR&D projects represent the fair value assigned to incomplete research projects that we acquire through business combinations, which at the time of acquisition, have not reached technological feasibility. For business combinations for which the acquisition date is before January 1, 2009, the fair value of such projects was expensed upon acquisition. For business combinations for which the acquisition date is on or after January 1, 2009, the fair value of a research projects is recognized as intangible asset on the consolidated balance sheet rather than expensed. The amounts capitalized are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, we will make a determination as to the useful life of the intangible asset and begin amortization. We test IPR&D for impairment at least annually and whenever impairment indicators are present. The impairment test consists of a comparison of the fair value of the IPR&D with its carrying amount. If the carrying amount of an IPR&D exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. Our IPR&D projects are still in progress. Based on our impairment testing, the fair value of IPR&D as of December 31, 2012 was less than the carrying amount, primarily due to lowered expectations for future sales and profitability of the vaccine products currently under development. RMB70.1 million (\$11.2 million) of impairment loss was recognized in 2012.

We have incurred research and development expenses of RMB125.7 million, RMB198.7 million and RMB228.7 million (\$36.7 million) in 2010, 2011 and 2012, respectively, representing, 5.9%, 9.7 % and 11.0% of our revenues, respectively. Our research and development capabilities have been recognized by various levels of the PRC government and we have received government funding in recognition of our capabilities. From January 1, 2010 to December 31, 2012, we recognized approximately RMB47.6 million (\$7.6 million) of government grants from the PRC government, which have been recorded as a reduction of our research and development expenses.

We are committed to increase our research and development capabilities, and expect to incur higher research and development expenses as we plan to supplement our development of first-to-market generic pharmaceuticals in China with increasing efforts in the research and development of innovative pharmaceuticals. Additionally, we have in the past sought, and may continue to seek, to acquire rights to development stage clinical products, technologies or suitable businesses that complement our expansion strategies and our existing products and products under development. To acquire these rights, we are required to utilize significant financial resources and incur increased in process research and development expense. Our research and development expenses also included depreciation of our new research facility after it was completed in January 2007.

Table of Contents

***Sales, Marketing and Distribution Expenses***

Sales, marketing and distribution expenses consist primarily of salaries and related expenses for personnel engaged in sales, marketing, distribution and customer support functions and costs associated with advertising and other marketing activities including expenses of engaging professional promotion and marketing companies. We host in-person product presentations, conference and seminars for physicians, other healthcare professionals and research scholars to promote and generate awareness of our pharmaceuticals. For our OTC pharmaceuticals, we also carry out consumer advertising and educational campaigns. As the pharmaceutical market in China continues to grow, we plan to further develop and strengthen our sales, marketing and distribution network in order to increase the market recognition of our products and our Simcere brand name. Sales, marketing and distribution expenses as a percentage of our revenues remained stable from 2010 to 2011 and decreased slightly from 2011 to 2012.

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and benefits for our administrative, finance and human resources personnel, depreciation of equipment and facilities of our administrative offices, amortization of rental facilities used for administrative purposes, bad debt expense, fees and expenses of legal, accounting and other professional services and other expenses associated with our administrative offices. General and administrative expenses decreased as a percentage of our revenues from 2011 to 2012, primarily due to a decrease in staff costs.

***Share-Based Compensation Expenses***

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

On April 15, 2009, our compensation committee approved a share option exchange program that offered our eligible directors, employees and consultants the right to exchange vested and unvested outstanding share options to purchase our ordinary shares granted under the 2006 Share Incentive Plan for our restricted shares. The exchange ratio was determined based on the fair value of replacement restricted shares so that the fair value of the replacement restricted shares to be issued upon exchange would be approximately equivalent to the fair value of the share options surrendered by an individual. In addition, these replacement restricted shares are subject to substantially the same vesting schedule as the options that are validly tendered in the exchange offer. A total of 154 directors and employees accepted the offer, and tendered options to purchase an aggregate of 9,802,400 ordinary shares in exchange for 1,833,990 vested shares and 2,916,028 non-vested shares on May 7, 2009. The exchange of the share option awards for restricted shares was accounted for as a modification of awards, which involves a cancellation of the original award and an issuance of a new award. The effect of this award modification on share-based compensation expense over the remaining requisite service period was insignificant.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

On October 14, 2009 and December 4, 2009, we granted 200,000 and 40,000 restricted shares to our officers and key employees under our 2006 share incentive plan, respectively.

Table of Contents

During 2010, we granted 870,000 restricted shares in total to our officers and key employees under our 2006 share incentive plan, including 480,000 restricted shares issued on March 9, 2010 to our independent directors and president. On September 1, 2010, we granted 978,000 options to our officers and key employees with an exercise price of \$4.545 per share. These options vest over a five-year period, with 20% of them vesting on September 1 of each year beginning from 2011.

In 2011, we granted 364,000 restricted shares in total to our officers and key employees under our 2006 share incentive plan.

In 2012, we granted 4,140,000 restricted shares in total to our directors, officers and key employees under our 2006 share incentive plan and granted 2,000,000 restricted shares to one of our directors under our 2008 share incentive plan.

We account for share-based compensation expenses based on the fair value of the share options on the date of the grant and recognize the amount over the requisite service period. We recognized share-based compensation expenses of RMB31.1 million, RMB29.3 million and RMB20.4 million (\$3.3 million) in 2010, 2011 and 2012, respectively. Share-based compensation expenses are allocated among each of research and development expenses, sales, marketing and distribution expenses and general and administrative expenses based on the nature of the work our employees were assigned to perform.

**Taxation and Incentives**

Effective from January 1, 2008, under the CIT law, the PRC's statutory income tax rate is 25%.

The CIT law and its relevant regulations provide a five-year transition period for those enterprises which were established before March 16, 2007 and which were entitled to a preferential income tax rate of 15% under the then effective tax laws and regulations, and also grandfather certain tax holidays until they expire. The transitional tax rates are 22%, 24% and 25% for 2010, 2011 and 2012 onwards, respectively.

Further, under the CIT law and its relevant regulations, entities that qualify as Advanced and New Technology Enterprises ( ANTEs ) are entitled to a preferential income tax rate of 15%.

On April 14, 2008, the Management Measures of Identifying Advanced and New Technology Enterprises and its annex, Key Fields of New and High-Tech Supported by the State, were issued jointly by the Ministry of Science and Technology, State Administration of Taxation and the Ministry of Finance, and outline the detailed procedures and measures to identify such ANTEs.

In 2008, Shandong Simcere, Jilin Boda and Simcere Zhong Ren were recognized by the PRC government as ANTEs under the CIT law and the related regulations, and were entitled to the preferential income tax rate of 15% from 2008 to 2010. In 2011, ANTE status of Shandong Simcere, Jilin Boda and Simcere Zhong Ren were renewed and entitled to the preferential tax rate of 15% from 2011 to 2013. In 2009, Nanjing Simcere

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

was recognized by the PRC government as an ANTE under the CIT law and the related regulations, and was entitled to the preferential tax rate of 15% from 2009 to 2011. In 2012, ANTE status of Nanjing Simcere was renewed and entitled to the preferential tax rate of 15% from 2012 to 2014. In 2011, Hainan Simcere was recognized by the PRC government as an ANTE under the CIT law and the related regulations, and was entitled to the preferential tax rate of 15% from 2011 to 2013.

Under the CIT law, where the transitional preferential income tax policies and the preferential policies prescribed under the CIT law and its implementation rules overlap, an enterprise shall choose to carry out the most preferential policy, but shall not enjoy multiple preferential policies. Nanjing Simcere and Shandong Simcere have chosen to enjoy the grandfathering treatment of the tax holiday of two-year 100% exemption followed by three-year 50% exemption until expiry in 2010 and 2011, respectively.



Table of Contents

Our effective income tax rates were 5.4%, negative 30.4% and 27.9% in 2010, 2011 and 2012, respectively. The lower effective income tax rate in 2010 resulted mainly from tax holidays and preferential tax rates enjoyed by some of our PRC subsidiaries during 2010, and for certain deferred tax assets, the effect of a higher tax rate applied for their future tax benefits. The negative effective income tax rate in 2011 resulted primarily from the reversal of a valuation allowance previously made against the deferred tax assets of Jiangsu Simcere amounting to RMB44.1 million and the impact of a non-taxable other operating income of RMB50.0 million arising from the receipt of a settlement in respect of the acquisition of Jiangsu Quanyi in 2009 from certain former shareholders of Jiangsu Quanyi. The reversal of a valuation allowance in Jiangsu Simcere was mainly attributable to the improved operating results.

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

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

**Critical Accounting Policies and the Use of Estimates**

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

Table of Contents

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

**Acquisitions**

On January 1, 2009, FASB ASC 805, *Business Combinations*, issued by the FASB was adopted which changes the way in which the acquisition method is to be applied in a business combination and also changes the way assets and liabilities are recognized in purchase accounting on a prospective basis. The acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values with limited exceptions. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recognized as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. If we determine the asset acquired does not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination, and therefore, no goodwill will be recognized. The fair value of intangible assets, including acquired IPR&D, is based on significant judgments made by us. Amounts allocated to acquired IPR&D are capitalized and accounted for similar to indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, we will make a separate determination as to the then useful life of the asset and begin amortization. The valuations and useful life assumptions are based on information available near the acquisition date and are based on expectations and assumptions that are deemed reasonable by us. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed, as well as asset lives, can materially affect our results of operations.

**Allowance for Doubtful Accounts**

We grant credit to a portion of our customers in the normal course of business depending on the customers' credit worthiness and the type of products we sell to them, although we require some customers to make payment prior to shipment. We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We determine the allowance by (1) analyzing specific customer accounts that have known or potential collection issues and (2) applying historical loss rates to the aging of the remaining accounts receivable balances. If circumstances related to specific customers change, our estimates of the recoverability of receivables could be further adjusted. In the event that we believe a trade receivable will become uncollectible, we record additional provision to increase the allowance for doubtful accounts. The accounting effect of this entry is a charge to income. We believe our allowance to doubtful accounts is sufficient to reflect the recoverability of our accounts receivable. If our business grows, we expect our accounts receivable balance to increase, as could our allowance for doubtful accounts. If the financial condition of our customers deteriorates, our uncollectible accounts receivable could exceed our current or future allowances. See Revenues. Our accounts and bills receivables as of December 31, 2012 decreased by RMB183.8 million (\$29.5 million) as compared to December 31, 2011, mainly due to our enhanced collection efforts. The following table presents the movement of allowance for doubtful accounts in 2010, 2011 and 2012:

	2010 RMB	Year Ended December 31,		2012 RMB	2012 \$
		2011 RMB	(in thousands)		
Beginning allowance for doubtful accounts	6,749	7,475	7,289		1,170
Additions charged to (reversal of) bad debt expense	843	994	(618)		(99)

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Write-off of accounts receivable	(117)	(1,180)		
<b>Ending allowance for doubtful accounts</b>	<b>7,475</b>	<b>7,289</b>	<b>6,671</b>	<b>1,071</b>

Table of Contents

***Inventories***

We value our finished goods inventory at the lower of cost, which consists of the cost of direct labor and raw materials as well as allocation of variable and fixed production overheads, and market value. Variable production overheads are allocated to each unit of production based on the actual use of the production facilities and fixed production overheads are allocated to the cost of conversion based on the normal capacity of the production facilities. We determine normal capacity as being a reasonable level of production volume supported by sufficient customer demand without any abnormal equipment downtime due to shortages of materials and labor. Expenses relating to abnormal levels of idle or excess facilities, spoilage and similar costs are expensed as incurred. In 2010, 2011 and 2012, we did not incur any significant abnormal amounts of idle facility expenses or spoilage as our manufacturing facilities were operating at normal capacity. Our inventory as of December 31, 2012 decreased by RMB5.8 million (\$0.9 million) as compared to December 31, 2011, primarily due to the reduction of packaging materials and finished goods in storage.

We write down the cost of inventory that we specifically identify and consider as obsolete. Finished goods inventory is considered obsolete when it has less than six months of remaining shelf life. Our raw materials and packaging materials are not subject to significant risk of obsolescence. We manage our inventory level based on our estimates of future demand within a specific time period, generally three months or less based on existing customer orders and, to a limited extent, forecasted customer orders. Given our manufacturing plan is primarily based on existing customer orders, we have recorded minimal inventory write-downs in the past. Our inventory write-downs for 2010, 2011 and 2012 were RMB4.8 million, RMB3.2 million and nil, respectively.

***Depreciation and Amortization***

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

Except for goodwill and IPR&D, we depreciate and amortize our long-lived assets using the straight-line method over the estimated useful lives of the assets. We make estimates of the useful lives of property, plant and equipment (including the salvage values) and intangibles, in order to determine the amount of depreciation and amortization expense to be recorded during any reporting period. We estimate the useful lives at the time we acquire the assets based on our historical experience with similar assets as well as anticipated technological or other changes. If technological changes were to occur more rapidly than anticipated or in a different form than anticipated, we might shorten the useful lives assigned to these assets, which will result in the recognition of increased depreciation and amortization expense in future periods. There has been no change to the estimated useful lives and salvage values in 2010, 2011 and 2012.

***Impairment of Long-Lived Assets and Goodwill***

As of December 31, 2012, our intangible assets primarily consisted of customer relationships, developed technologies, product trademarks and IPR&D that we acquired in connection with our acquisition of 90.0% of the equity interest in Shandong Simcere in 2006 and 2007, 51.0% equity interest in Jilin Boda in 2007, 85.7% equity interest in Nanjing Tung Chit in 2007, 70.0% equity interest in Simcere Zhong Ren in 2008, and 52.5% equity interest in Jiangsu Quanyi in 2009, as well as the acquired technology know-how of Iremod and Rosuvastatin from third parties.



Table of Contents

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

For IPR&D, the fair value was determined using an income approach, through which fair value is estimated based on each asset's probability adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

We evaluate long-lived assets, including property, plant and equipment and intangible assets with definite lives for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We assess recoverability by comparing the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. We recognize an impairment charge based on the amount by which the carrying amount of the asset exceeds the fair value of the asset. We determine fair value based on either market quotes, if available, or discounted cash flows using a discount rate commensurate with the risk inherent in our current business model for the specific asset being valued. Major factors that influence our cash flow analysis are our estimates for future revenues and expenses associated with the use of the asset. No impairment charge was recognized on long-lived assets or asset groups held and used including property, plant and equipment and intangible assets with definite lives in 2010, 2011 and 2012.

We evaluate IPR&D for impairment at least annually or whenever impairment indicators are present. The impairment test consists of a comparison of the fair value of the IPR&D with its carrying amount. For impairment testing purposes, we combine IPR&D if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, we recognize an impairment loss based on the amount by which the carrying amount of the asset exceeds the fair value of the asset. Our IPR&D balance as of December 31, 2012 related to our acquisition of 52.5% equity interest in Jiangsu Quanyi in 2009. Our IPR&D projects are still in progress. Considering that our business strategy will focus on the pharmaceutical business, we reassessed the commercialization of in-process R&D projects of vaccine business and revised the vaccine business plan. Based on our impairment testing, the fair value of IPR&D as of December 31, 2012 was less than the carrying amount, primarily due to lowered expectations for future sales and profitability of the vaccine products currently under development. RMB70.1 million (\$11.2 million) of impairment loss was recognized in 2012.

Table of Contents

We evaluate goodwill at reporting level at least annually for impairment, and more frequently if events and circumstances indicate that it might be impaired. A reporting unit is an operating segment or one level below an operating segment (referred to as a component). A component of an operating segment is a reporting unit if the component constitutes a business for which discrete financial information is available and segment management regularly reviews the operating results of that component. When two or more components of an operating segment have similar economic characteristics, the components shall be aggregated and deemed a single reporting unit. An operating segment shall be deemed to be a reporting unit if all of its components are similar, if none of its components is a reporting unit, or if the segment comprises only a single component.

We may first assess qualitative factors to determine whether it is necessary to perform the two-step impairment test. We can choose to perform the qualitative assessment on none, some or all of its reporting units. We can bypass the qualitative assessment for any reporting unit in any period and proceed directly to step one of the impairment test, and then resume performing the qualitative assessment in any subsequent period. If a qualitative assessment is not performed, or if as a result of a qualitative assessment it is not more likely than not that the fair value of a reporting unit exceeds its carrying value, then the two-steps impairment test is performed.

The first step of the impairment test involves comparing the fair value of each of our reporting units with their respective carrying amounts, including allocated goodwill. Secondly, if the carrying amount of a reporting unit exceeds its fair value, we then recognize an impairment loss for any excess of the carrying amount of the reporting unit's goodwill over the implied fair value of that goodwill. We determine the implied fair value of goodwill by allocating the fair value of the reporting unit in a manner similar to a purchase price allocation. The residual fair value after this allocation is the implied fair value of the reporting unit goodwill.

Following the acquisition of Jiangsu Quanyi in 2009, we evaluated and determined that there are two reporting units, a pharmaceutical reporting unit and a vaccine reporting unit, for goodwill impairment testing. In 2009, 2011 and 2012, we used a discounted cash flow analysis to determine the fair value of our reporting units.

The determination of fair value of the reporting units and assets and liabilities within the reporting units required us to make significant estimates and assumptions. The estimates and assumptions primarily include, but are not limited to, revenue growth rates, gross margin percentages, earning before depreciation and amortization, projected working capital needs, capital expenditures forecasts, discount rates and terminal growth rates. Due to the inherent uncertainty involved in making these estimates, actual results could differ from those estimates. To determine fair value, we discount the expected cash flows of each reporting unit. The discount rate used represents the estimated weighted average cost of capital, which reflects the overall level of inherent risk involved in its reporting units operations and the rate of return an outside investor would expect to earn. To estimate cash flows beyond the final year of its model, we use a terminal value approach. Under this approach, we use the estimated cash flows in the final year of its model and apply a perpetuity growth assumption and discount the relative cash flows by a perpetuity discount factor to determine the terminal value. We incorporate the present value of the resulting terminal value into our estimate of fair value.

In determining the fair value of the vaccine reporting unit as of December 31, 2010, we used a discount rate of 17% in discounting the cash flow estimates. We assumed that Jiangsu Quanyi and Jiangsu Vaxtec would be able to successfully renew and obtain a GMP certificate for the influenza vaccine and resume production, sales and marketing activities in the second half of 2011. We also assumed reduced cash flows from sales for the period from the second half of 2011 to 2013, the period which we believe will be required to rebuild the brand and regain market share. Based on impairment testing, the fair value of the vaccine reporting unit as of December 31, 2010 was greater than the carrying amount of the vaccine reporting unit.





Table of Contents

We were unable to obtain the GMP certificate for the influenza vaccine as planned in 2011 as a result of the changes to the GMP standards and its implementation rules, which impose additional requirements on the GMP review process, including requiring additional analysis on risk controls. In addition, we upgraded our production lines for influenza vaccine to further improve our manufacturing processes and techniques. To reflect the increased risk resulting from the delay in GMP certificate application, in determining the fair value of the vaccine reporting unit as of December 31, 2011, we used a higher discount rate of 18.5% in discounting the cash flow estimates. We assumed that Jiangsu Vaxtec would be able to successfully renew and obtain a GMP certificate for its influenza vaccine and resume production, sales and marketing activities in the second half of 2012. We also assumed reduced cash flows from sales for the period from the second half of 2012 to 2014, the period which we believe will be required to rebuild the brand and regain market share. Based on impairment testing, the fair value of the vaccine reporting unit as of December 31, 2011 was greater than the carrying amount of the vaccine reporting unit.

Jiangsu Vaxtec obtained a GMP certificate for its influenza vaccine and commenced production in March 2013. In determining the fair value of the vaccine reporting unit as of December 31, 2012, we used a discount rate of 19% in discounting the cash flow estimates. We also assumed reduced cash flows from influenza vaccine sales for the period from 2013 to 2015, the period in which we believe will be required to rebuild the brand and regain market share, as well as reduced cash flows of the vaccine products currently under development due to lowered expectations for future sales and profitability of these products because the Group's business strategy will focus on pharmaceutical business. Based on impairment testing, the fair value of the vaccine reporting unit as of December 31, 2012 was less than the carrying amount of the vaccine reporting unit. RMB25.3 million (\$4.1 million) of goodwill impairment loss has been recognized in 2012.

As of December 31 2012, our goodwill balance was RMB284.6 million (\$45.7 million), including RMB106.4 million of goodwill related to our acquisition of a 52.5% equity interest in Jiangsu Quanyi in 2009, which also reflected the impairment charge of RMB76.4 million we recognized for the vaccines reporting unit in 2009, and RMB25.3 million (\$4.1 million) we recognized in 2012. We determined that no impairment loss was required to be recognized for our pharmaceutical reporting units in 2011 and 2012.

Significant judgment was involved in determining the impact of the suspension order of Jiangsu Quanyi on the cash flows of the vaccine reporting unit, including the period of time Jiangsu Vaxtec will take to resume production and regain market share. Assumptions used in our impairment analysis, such as forecast revenues, growth rates and cost of capital, are consistent with our current business plan and internal cash flows projection for the vaccine reporting unit. Changes in projections or estimates could significantly change the estimated fair value of the vaccine reporting unit. If we used different assumptions or estimates, the goodwill impairment charge and the operating results could be different.

***Share-based Compensation***

We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award and recognize that cost in our consolidated statements of comprehensive income over the period during which an employee is required to provide service in exchange for the award.

We determined the fair value of options using the Black-Scholes option pricing model. Under this option pricing model, certain assumptions, including the risk-free interest rate, the expected term of the options, the expected dividends on the underlying ordinary shares, and the expected volatility of the price of the underlying share for the expected term of the option, are required in order to determine the fair value of the options.

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

In 2010, 2011 and 2012, 978,000, nil and nil share options were granted under our 2006 Share Incentive Plan.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

The assumptions used in determining the fair value of the share options granted in 2010 are shown at their weighted average values as follows:

	<b>Year Ended December 31, 2010</b>
Valuation assumptions	
Expected term (in years)	4.5
Expected volatility	64.73%
Expected dividend	0%
Risk-free rate	0.75%-1.41%

Since the share options granted prior to year 2009 were exchanged to non-vested shares in May 2009, we are not able to rely on historical exercise data to estimate the expected term of the share options granted in 2010. Accordingly, the expected term is based on the simplified method by averaging the vesting term and contractual term. We used the historical volatility of our shares to estimate the expected volatility. The risk-free rate is based on the yield of the United States Treasury bond rate.

### *Income tax uncertainties and realization of deferred tax assets*

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

As of December 31, 2011 and 2012, we had total gross deferred tax assets of RMB134.0 million and RMB163.8 million (\$26.3 million), respectively. We record a valuation allowance to reduce our deferred tax assets if, based on the weight of available evidence, we believe expected future taxable income is more likely than not that all or some portion of the asset will not be realized by sufficient taxable income in the period necessary to utilize the benefit of the deferred tax asset. We evaluate the level of our valuation allowances quarterly, and more frequently if actual operating results differ significantly from forecasted results. As of December 31, 2011 and 2012, our valuation allowances for deferred tax asset were RMB2.3 million and RMB7.8 million (\$1.2 million), respectively. Our valuation allowances increased by RMB5.5 million (\$0.9 million) in 2012, which was primarily attributable to valuation allowance of RMB7.4 million (\$1.2 million) provided against the deferred tax assets of Sichuan Simcere and Jiangsu Quanyi, which was offset by the reversal of valuation allowance provided against the deferred tax assets of Simcere America of RMB2.0 (\$0.3 million). Simcere America generated taxable income in 2012 and expects to generate further taxable income for it to utilize or recover its deferred tax assets.

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

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

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

Table of Contents**Results of Operations**

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

	2010		Year Ended December 31, 2011		2012	
	RMB	% of Total Revenues	RMB (in thousands, except percentages)	% of Total Revenues	RMB	% of Total Revenues
Revenue	2,141,098	100.0	2,040,547	100.0	2,082,966	100
Cost of materials and production	(341,787)	(16.0)	(328,159)	(16.1)	(361,071)	(17.3)
Gross profit	1,799,311	84.0	1,712,388	83.9	1,721,895	82.7
Operating expenses:						
Research and development	(125,737)	(5.9)	(198,722)	(9.7)	(228,717)	(11.0)
Sales, marketing and distribution	(1,186,144)	(55.4)	(1,131,974)	(55.5)	(1,140,810)	(54.8)
General and administrative	(269,512)	(12.6)	(288,144)	(14.1)	(255,999)	(12.3)
Impairment charges					(97,247)	(4.6)
Total operating expenses	(1,581,393)	(73.9)	(1,618,840)	(79.3)	(1,722,773)	(82.7)
Gain arising from loss of control of a subsidiary					24,789	1.2
Other operating income			50,000	2.4	15,650	0.7
Income from operations	217,918	10.1	143,548	7.0	39,561	1.9
Interest income	4,214	0.2	4,676	0.2	4,066	0.2
Interest expense	(19,920)	(0.9)	(42,342)	(2.0)	(69,258)	(3.3)
Foreign currency exchange gains (losses), net	5,511	0.3	7,732	0.4	(923)	(0.1)
Other income	2,286	0.1	15,036	0.7	11,429	0.5
Equity in losses of equity method affiliated companies	(14,716)	(0.7)	(12,192)	(0.6)	(4,859)	(0.2)
Earnings (losses) before income taxes	195,293	9.1	116,458	5.7	(19,984)	(1.0)
Income tax (expense) benefit	(10,640)	(0.5)	35,371	1.7	5,581	0.3
Net income	184,653	8.6	151,829	7.4	(14,403)	(0.7)
Net (income) loss attributable to the redeemable and other noncontrolling interest	(12,242)	(0.5)	26,560	1.3	71,360	3.4
Net income attributable to Simcere Pharmaceutical Group(1)	172,411	8.1	178,389	8.7	56,957	2.7

---

(1) Certain of our PRC operating subsidiaries were entitled to a tax holiday in 2010 and 2011. The effect of the tax holiday increased our net income for 2010 and 2011 by RMB29.9 million and RMB7.0 million, respectively, or 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.

**Comparison of Years Ended December 31, 2011 and December 31, 2012**

**Revenues.** Our revenues represent the invoiced value of products sold, net of VAT. Our revenues increased by 2.1% to RMB2,083.0 million (\$334.3 million) in 2012 from RMB2,040.5 million in 2011. This increase was primarily due to increases in the sales of Zailin, Endu, Nuowei, Iremod and Shufutan, partially offset by decreases in the sales of Bicun, Yidasheng and Sinofuan. Revenues from Bicun decreased to RMB612.2 million (RMB98.3 million) in 2012, representing 29.4% of our revenues, from RMB654.6 million in 2011, or 32.1% of our revenues. The decrease in sales of Bicun resulted from changes to the tender process in certain provinces and competitive market competition. The decrease in sales of Sinofuan resulted primarily from a decrease in selling price.

Table of Contents

**Gross Profit and Gross Margin.** Our gross profit increased by 0.6% to RMB1,721.9 million (\$276.4 million) in 2012 from RMB1,712.4 million in 2011. Our gross margin slightly decreased to 82.7% in 2012 from 83.9% in 2011, primarily due to the decrease in sales percentage of drugs with higher gross margin and the price decrease of certain drugs.

**Operating Expenses.** Our operating expenses increased by 6.4% to RMB1,722.8 million (\$276.5 million) in 2012 from RMB1,618.8 million in 2011. Operating expenses as a percentage of our revenues increased to 82.7% in 2012 from 79.3% in 2011.

- **Research and Development Expenses.** Our research and development expenses increased to RMB228.7 million (\$36.7 million) in 2012 from RMB198.7 million in 2011. Research and development expenses as a percentage of our revenues increased to 11.0% in 2012 from 9.7% in 2011. The increase in research and development expenses was primarily due to increased staff costs as a result of an increase in headcount, an increase in depreciation and decreased government research and development grants recognized in 2012.

- **Sales, Marketing and Distribution Expenses.** Our sales, marketing and distribution expenses increased by 0.8% to RMB1,140.8 million (\$183.1 million) in 2012 from RMB1,132.0 million in 2011. Sales, marketing and distribution expenses as a percentage of our revenues slightly decreased to 54.8% in 2012 compared to 55.5% in 2011.

- **General and Administrative Expenses.** Our general and administrative expenses decreased by 11.2% to RMB256.0 million (\$41.1 million) in 2012 from RMB288.1 million in 2011. The decrease was primarily related to the decrease of staff costs. General and administrative expenses as a percentage of our revenues decreased to 12.3% in 2012 from 14.1% in 2011.

- **Impairment Charges.** Because our business strategy will focus on pharmaceutical business, we reassessed the commercialization of in-process R&D projects of vaccine business and vaccine business plan. Based on our impairment testing, the fair value of IPR&D and vaccine reporting unit as of December 31, 2012 was less than the carrying amount, primarily due to lowered expectation for future sales and profitability of the vaccine products currently under development. Therefore, RMB70.1 million (\$11.2 million) and RMB25.3 million (\$4.1 million) of impairment loss on IPR&D and goodwill of vaccine reporting unit were recognized in 2012.

**Gain arising from loss of control of a subsidiary.** The gain arose from the disposal of the controlling interest on one of our subsidiaries as part of the establishment of our equity joint venture with Merck.

**Other operating income.** In 2009, we acquired 100% equity interest in China Vax, which is a Cayman Islands investment holding company and holds 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 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 USD2.5 million (RMB15.6 million) was recognized as other operating income in 2012.

**Interest Income.** Our interest income slightly decreased to RMB4.1 million (\$0.7 million) in 2012 from RMB4.7 million in 2011.





## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

**Interest Expense.** Our interest expense increased by 63.6% to RMB69.3 million (\$11.1 million) in 2012 from RMB42.3 million in 2011. This increase was primarily due to increased cost of bank borrowing and bills receivable discounting.

**Foreign Currency Exchange Gains (losses), Net.** Our foreign currency exchange losses totaled RMB0.9 million (\$0.1 million) in 2012, representing realized gains resulting from the repayment of the loans. As these intercompany loans are not considered long-term investment in nature and given the functional currency of our holding company is U.S. dollar and the functional currency of our PRC subsidiaries is Renminbi, gains or losses arising from the translation of the intercompany loans from U.S. dollars to Renminbi by our PRC subsidiaries is recognized in our consolidated statements of comprehensive income while gains and losses arising from the translation of our company's U.S. dollars financial statements to Renminbi for consolidation purpose is recognized in our consolidated statement of change in shareholders' equity.

**Other Income.** Our 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 refunds granted by local governments.

**Equity in Losses of Equity Method Affiliated Companies.** Our equity in losses of equity method affiliated companies in 2012 represented the share of loss of our 35.0% equity interest in Shanghai Celgent amounting to RMB10.2 million (\$1.6 million), net off by the share of profit of our 49% equity interest in Simcere MSD (Shanghai) Pharmaceutical Co., Ltd. or Simcere SMSD amounting to RMB5.3 million (\$0.8 million).

**Income Tax (Expense) Benefit.** Our effective income tax rates in 2011 and 2012 were negative 30.4%, and 27.9% respectively. The negative effective income tax rate in 2011 resulted primarily from the reversal of a valuation allowance previously made against the deferred tax assets of Jiangsu Simcere amounting to RMB44.1 million, and the impact of a non-taxable other operating income received of RMB50.0 million arising from the receipt of settlement payment in respect of the acquisition of Jiangsu Quanyi in 2009. The reversal of a valuation allowance of Jiangsu Simcere was mainly attributable to its improved operating results.

**Net (Income) Loss Attributable to the Redeemable and Other Noncontrolling Interest.** Net loss attributable to the redeemable and other noncontrolling interests of RMB71.4 million (\$11.5 million) in 2012 primarily represented share of the noncontrolling interests in the operating loss in Jiangsu Quanyi and Jiangsu Vaxtec, which was partially offset by share of the noncontrolling interest in the operating profits in Simcere Zhong Ren and Jilin Boda.

**Net Income Attributable to Simcere Pharmaceutical Group.** As a result of the foregoing, our net income decreased by 68.1% to RMB57.0 million (\$9.1 million) in 2012 from RMB178.4 million in 2011, while net margin decreased to 2.7% in 2012 from 8.7% in 2011.

### **Comparison of Years Ended December 31, 2010 and December 31, 2011**

**Revenues.** Our revenues represent the invoiced value of products sold, net of VAT. Our revenues decreased by 4.7% to RMB2,040.5 million in 2011 from RMB2,141.1 million in 2010. This decrease was primarily due to decreases in the sales of Zailin and Bicun, partially offset by the increases in the sales of Endu, Sinofuan, Anxin and Jiebaishu. Revenues from sales of Zailin decreased to RMB191.0 million in 2011, representing 9.4% of our revenues, from RMB320.8 million in 2010, or 15.0% of our revenues. The significant decrease in revenues from sales

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

of Zailin resulted primarily from government policies of controlling pharmaceutical prices. Revenues from Bicun decreased to RMB654.6 million in 2011, representing 32.1% of our revenues, from RMB667.7 million in 2010, or 31.2% of our revenues. The decrease in sales of Bicun resulted from changes to the tender process in certain provinces and reorganization of our sales force in some regional markets.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

**Gross Profit and Gross Margin.** Our gross profit decreased by 4.8% to RMB1,712.4 million in 2011 from RMB1,799.3 million in 2010. Our gross margin slightly decreased to 83.9% in 2011 from 84.0% in 2010.

**Operating Expenses.** Our operating expenses increased by 2.4% to RMB1,618.8 million in 2011 from RMB1,581.4 million in 2010. Operating expenses as a percentage of our revenues increased to 79.3% in 2011 from 73.9% in 2010.

- **Research and Development Expenses.** Our research and development expenses increased to RMB198.7 million in 2011 from RMB125.7 million in 2010. Research and development expenses as percentage of our revenues increased to 9.7% in 2011 from 5.9% in 2010. The increase in research and development expenses was primarily due to increased expenditures on on-going research and development projects and an increase in research and development personnel.

- **Sales, Marketing and Distribution Expenses.** Our sales, marketing and distribution expenses decreased by 4.6% to RMB1,132.0 million in 2011 from RMB1,186.1 million in 2010. Sales, marketing and distribution expenses as a percentage of our revenues remained stable at 55.5% in 2011 compared to 55.4% in 2010.

- **General and Administrative Expenses.** Our general and administrative expenses increased by 6.9% to RMB288.1 million in 2011 from RMB269.5 million in 2010. The increase was primarily related to the increase of staff costs as well as legal fees for the establishment of an equity joint venture with an affiliate of Merck. General and administrative expenses as a percentage of our revenues increased to 14.1% in 2011 from 12.6% in 2010.

**Other operating income.** We reached a settlement agreement with the former shareholders and former directors of Jiangsu Quanyi in 2011 in respect of our acquisition of a 37.5% equity interest in Jiangsu Quanyi in 2009. Pursuant to the settlement agreement, we received total cash compensation of RMB50.0 million in 2011, which was recognized as other operating income.

**Interest Income.** Our interest income slightly increased to RMB4.7 million in 2011 from RMB4.2 million in 2010.

**Interest Expense.** Our interest expense increased by 112.6% to RMB42.3 million in 2011 from RMB19.9 million in 2010. This increase was primarily due to increased cost of bank financing and balances of loans.

**Foreign Currency Exchange Gains, Net.** Our foreign currency exchange gains totaled RMB7.7 million in 2011, representing unrealized gains resulting from the translation of U.S. dollar-denominated intercompany loans to our PRC subsidiaries that were converted to Renminbi and realized gains resulting from the repayment of the loans. As these intercompany loans are not considered long-term investment in nature and given the functional currency of our holding company is U.S. dollars and the functional currency of our PRC subsidiaries is Renminbi, gains or losses arising from the translation of the intercompany loans from U.S. dollars to Renminbi by our PRC subsidiaries is recognized in our consolidated statements of comprehensive income while gains and losses arising from the translation of our company's U.S. dollars financial statements to Renminbi for consolidation purpose is recognized in our consolidated statement of shareholders' equity and comprehensive income.

**Other Income.** Our other income included the incentive payment received from our depository in connection with the establishment of the ADR program following our initial public offering and tax refunds granted by local governments. The increase in other income to RMB15.0 million in 2011 from RMB2.3 million in 2010 was mainly contributed by the tax refunds granted by local governments.

Table of Contents

**Equity in Losses of Equity Method Affiliated Companies.** Our equity in losses of equity method affiliated companies in 2011 represented the share of loss of our 35.0% equity interest in Shanghai Celgen amounting to RMB12.2 million, compared to RMB14.7 million in 2010.

**Income Tax Expense (Benefit).** Our effective income tax rates in 2010 and 2011 were 5.4% and negative 30.4%, respectively. The lower effective income tax rate in 2010 resulted mainly from tax holidays and preferential tax rates enjoyed by some of our PRC subsidiaries during 2010 and, for certain deferred tax assets, the effect of a higher tax rate applied for their future tax benefits. The negative effective income tax rate in 2011 resulted primarily from the reversal of a valuation allowance previously made against the deferred tax assets of Jiangsu Simcere amounting to RMB44.1 million, and the impact of a non-taxable other operating income received of RMB50.0 million arising from the receipt of settlement payment in respect of the acquisition of Jiangsu Quanyi in 2009. The reversal of a valuation allowance of Jiangsu Simcere was mainly attributable to its improved operating results. Jiangsu Simcere generated taxable income in 2011 and expects to generate further taxable income for it to utilize or recover its deferred tax assets.

**Net (Income) Loss Attributable to the Redeemable Noncontrolling Interest and Noncontrolling Interest.** Net loss attributable to the noncontrolling interests of RMB26.6 million in 2011 primarily represented our share of the noncontrolling interests in the operating loss in Jiangsu Quanyi and Jiangsu Vaxtec, which was partially offset by share of operating profits in Jilin Boda and Simcere Zhong Ren.

**Net Income Attributable to Simcere Pharmaceutical Group.** As a result of the foregoing, our net income increased by 3.5% to RMB178.4 million, in 2011 from RMB172.4 million in 2010, while net margin increased to 8.7% in 2011 from 8.1% in 2010.

**Inflation**

In recent years, China has not experienced significant inflation, and thus inflation has not had a material impact on our results of operations. According to the PRC National Bureau of Statistics, the change in Consumer Price Index in China was 3.3%, 5.4% and 2.6% in 2010, 2011 and 2012, respectively.

*B. Liquidity and Capital Resources*

**Liquidity and Capital Resources**

Following is a summary of our net cash flows for the years indicated:

	Year Ended December 31,			
2010	2011	2012	2012	
RMB	RMB	RMB	\$	

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

	(in thousands)			
Net cash provided by (used in) operating activities	132,260	(176,893)	313,578	50,333
Net cash used in investing activities	(202,205)	(228,181)	(65,629)	(10,534)
Net cash provided by (used in) financing activities	(97,738)	342,948	(279,583)	(44,876)
Effect of exchange rate changes on cash	(1,222)	(1,607)	(54)	(9)
Net decrease in cash	(168,905)	(63,733)	(31,688)	(5,086)
Cash at beginning of year	442,488	273,583	209,850	33,683
Cash at end of year	273,583	209,850	178,162	28,597

As of December 31, 2011 and 2012, we had RMB209.9 million and RMB178.2 million (\$28.6 million) in cash, respectively. Our cash primarily consists of cash on hand, cash deposited in banks and interest-bearing savings accounts. The decrease in cash was primarily due to the combined effects of the cash provided by operating activities, payments for purchase of property, plant and equipment, payments for establishment of an affiliated company, the repurchase of our ordinary shares, and repayments of bank loans and other borrowings.

Table of Contents

*Operating Activities*

Cash flows from operating activities changed from net outflows in 2011 to net inflows in 2012, which was primarily due to the accelerated collection of accounts receivable and discount of bills receivable.

*Investing Activities*

Net cash used in investing activities was RMB65.6 million (\$10.5 million) during 2012, mainly for payments for purchase of property, plant and equipment and establishment of an affiliated company.

Net cash used in investing activities was RMB228.2 million during 2011, mainly for the purchase of property, plant and equipment and intangible assets, and payments of deposits for the purchase of property, plant and equipment, intangible assets and land use rights of RMB216.6 million.

*Financing Activities*

Net cash used in financing activities was RMB279.6 million (\$44.9 million) during 2012, primarily due to repurchase of our ordinary shares of RMB121.9 million (\$19.6 million), and repayments of bank loans, partially offset by proceeds from bank loans amounting to RMB138.4 million (\$22.2 million).

Net cash provided by financing activities was RMB342.9 million during 2011, primarily due to proceeds from bank borrowings of RMB436.8 million partially offset by our payment for the acquisition of 39.19% and 9.80% equity interest in Jinlin Boda for cash consideration of RMB52.8 million and repurchase of our ordinary shares of RMB32.0 million.

We believe that our current levels of cash and cash flows from operating activities and bank borrowings will be sufficient to meet our anticipated cash needs and commitments, including our working capital needs, for at least the next 12 months. However, we may need additional cash resources in the future if we experience changed business conditions or other developments. We may also need additional cash resources in the future if we find and wish to pursue opportunities for investment, acquisition, strategic cooperation or other similar actions. If we ever determine that our cash requirements exceed our amounts of cash on hand, we may seek to issue debt or equity securities or obtain a credit facility. Any issuance of equity securities could cause dilution for our shareholders. Any incurrence of indebtedness could increase our debt service obligations and cause us to be subject to restrictive operating and finance covenants. It is possible that, when we need additional cash resources, financing will only be available to us in amounts or on terms that would not be acceptable to us or financing will not be available at all.

**Capital expenditures**

In 2010, 2011 and 2012, our capital expenditures totaled RMB188.8 million, RMB216.6 million and RMB54.0 million (\$8.7 million), respectively. In past years, our capital expenditures consisted primarily of the costs of obtaining land use rights and the purchases of property, plant and equipment and our research and development facilities. Our capital expenditures in 2013 will be used mainly for the payments for the purchase of property, plant and equipment. We expect to use cash generated by operating activities to pay for our capital expenditures in 2013.



Table of Contents

C. *Research and Development, Patents and Licenses, etc*

**Our Strategy**

We aim to balance our research and development efforts between the development of first-to-market generic pharmaceuticals and innovative pharmaceuticals. We perform thorough market analysis before commencing a research and development project to determine whether the pharmaceutical is commercially viable, is able to achieve widespread acceptance in the marketplace, and for new generic pharmaceuticals, whether such generic pharmaceutical will be the first generic version on the market. We focus our research and development efforts on pharmaceuticals used to treat diseases with a high incidence and/or mortality rate that, at the same time, lack effective pharmacotherapy, such as cancer, cerebrovascular diseases, rheumatoid arthritis and infectious diseases. Our vaccine research is also focused on diseases with high incidence of occurrences. We believe such research and development strategy will lead to the development of products that have a high potential for commercialization and can maximize our growth rate and profit margins. In addition, we will continue to enhance our existing portfolio of pharmaceuticals by improving their convenience (such as the reduction in the frequency of administering medicines) and/or their therapeutic benefits. Our research and development team also assists our manufacturing division in resolving technical issues and improving manufacturing processes and techniques.

**Our Capability**

As of March 31, 2013, we had 315 research staff members, 157 of whom held master's degrees and 40 of whom held Ph.D. degrees, including 23 staff members with overseas training and/or work experience. Our research and development activities are primarily conducted by our operating subsidiaries in China, Jiangsu Simcere Pharmaceutical R&D Co., Ltd., or Simcere Research, located in Nanjing, Jiangsu Province, and Shanghai Simcere Pharmaceutical R&D Co., Ltd., located in Shanghai. See Item 4. Information on the Company B. Business Overview Our Products Our Innovative Pharmaceutical Endu (Recombinant Human Endostatin Injection) for more information as to our anti-cancer research and development activities. We have several technology platforms and are capable of conducting research on both chemical pharmaceuticals and biopharmaceuticals. We have also established a post-doctoral research program in December 2003 through our research facility in Nanjing, where we offer post-doctoral researchers the opportunity to conduct innovative research and development projects under the guidance of our internal and external research scientists. We believe our post-doctoral program provides us with a means to attract top academic talent to join our company. As of December 31, 2012, we had 12 post-doctoral researchers participating in this program.

**Collaborative Research**

In September 2007, our subsidiary Simcere Research entered into a technology development agreement with China Pharmaceutical University to develop Endu as a long acting pharmaceutical through the PEGylation process. The PEGylated Endu will reduce the number of times for which Endu is required to be administered to once every week or two weeks. The amount to be paid under the agreement is RMB2.9 million and as of March 31, 2013, Simcere Research has paid an aggregate of RMB1.3 million (\$0.2 million). In addition, Simcere Research has agreed under the agreement to transfer to China Pharmaceutical University 0.5% of the total revenues derived from the sales of this pharmaceutical every year for three years upon successfully obtaining new medicine certificate. The pre-clinical trials of PEGylated Endu were completed and we applied with the CFDA for clinical testing in July 2011.



Table of Contents

We also entered into an agreement in January 2007 with Advenchen, a pharmaceutical research and development company in the United States as a research partner to engage in the research and development of, clinical studies for, and the commercialization of an anti-cancer pharmaceutical based on a chemical compound owned by Advenchen. Under the terms of the agreement, we agreed to provide research assistance and funding of up to RMB30.0 million of which RMB2.0 million was provided in February 2007. We provided an additional RMB1.0 million upon receiving three successful batches of anti-cancer pharmaceutical samples in July 2007. Another RMB1.0 million was paid upon the launch of the pre-clinical study in July 2008. In 2011, we paid RMB6.0 million upon receipt of the IND approval from CFDA. The remaining RMB20.0 million will be further provided if additional milestones as set forth under the agreement are achieved. We also have a right to terminate the agreement if Advenchen cannot successfully obtain a valid invention patent in China for the chemical compound it owns at which point we will terminate any further research and development activities under the agreement, and Advenchen will refund half of the funding already provided to it under the agreement. Pursuant to the agreement, we will be entitled to all intellectual property rights, the right to commercialize and all interests in the anti-cancer pharmaceutical in China, and will share equally with Advenchen the intellectual property rights outside of China. In addition, we will pay Advenchen 3.5% of total revenues from the sales of the anti-cancer pharmaceutical in China, deducting the costs of packing, transportation, advertising and marketing, taxation, discounts and other relevant costs, until the expiration of its patent period, provided that the anti-cancer pharmaceutical is successfully developed and commercialized. We began in 2008 pre-clinical trials of the anti-cancer pharmaceutical under the agreement, including the pharmacodynamics research on lung cancer, animal pharmacokinetics research and safety evaluation research, and completed the pre-clinical studies by the end of 2009. We have applied with the CFDA for clinical testing in 2010 and obtained the IND approval from the CFDA in 2011.

On December 12, 2008, we entered into an agreement to collaborate on the co-development and production of humanized RabMAb ® antibody therapeutics for tumors with Epitomics, Inc., a provider of humanized rabbit monoclonal antibodies for therapeutic use. Under the agreement, we and Epitomics, Inc. will collaborate on pre-clinical and clinical trials, product manufacturing, and product distribution in the international markets. We will have the exclusive production and distribution rights in China. We agreed to pay a total funding of up to \$5.0 million of which \$1.0 million was paid to acquire the license rights of in-process R&D materials in January 2009. The remaining \$4.0 million will be provided at various dates upon the achievement of certain milestones as set forth under the agreement. The pre-clinical studies were completed and we have applied with the CFDA for clinical testing at the end of 2010, and obtained the IND approval from the CFDA in 2012. According to the agreement, we will hold the rights to commercialize the drug in China and Epitomics, Inc. will hold the rights to commercialize the drug outside China. In addition, if the anti-cancer pharmaceutical is successfully developed and commercialized, we will pay Epitomics, Inc. royalties on the net sales derived from the sales of this drug in China upon achieving certain agreed annual net sales level.

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

In October 2009, we entered into an agreement with OSI Pharmaceuticals, Inc., a NASDAQ-listed pharmaceutical company specialized in discovery and development of innovative molecular targeted therapies, to develop, manufacture, and market its KDR/Kit inhibitor OSI-930 in China. Under the agreement, we agreed to provide a fixed amount of funding. A portion of which was paid to acquire the license right of technical know-how, while the remaining will be provided at various dates upon the achievement of certain milestones as set forth under the agreement. OSI-930 is an orally active inhibitor of two clinically validated targets: c-Kit and the vascular endothelial growth factor receptor-2 (VEGFR-2). OSI-930 is designed to target both cancer cell proliferation and blood vessel growth (angiogenesis) in selected tumors. In preclinical studies, OSI-930 shows broad efficacy in tumor models representative of small cell lung cancer, glioblastoma, colorectal, renal, head and neck, non-small cell lung cancer and gastric cancers. We applied with the CFDA for clinical testing in 2010.

Table of Contents

In November 2010, we formed a strategic partnership with Bristol-Myers Squibb, or BMS, to co-develop BMS-817378, a pre-clinical small molecule MET/VEGFR-2 inhibitor. Under the agreement, we will receive exclusive rights to develop and commercialize BMS-817378 in China while BMS will retain exclusive rights in all other markets. The parties will together determine the strategic development plan, which will initially be implemented by us. This arrangement represents a creative approach to accelerate the development process from preclinical oncology compound to clinical proof-of-concept by leveraging the complementary strengths of a premier Chinese pharmaceutical company and a global pharmaceutical company. We completed preclinical studies and submitted IND application in October 2011, and obtained the IND approval from the CFDA in 2012.

In May 2011, we entered into a strategic research and development collaboration agreement with Nanjing Medical University to develop SIM11057, a stroke management medication with novel mechanism and target.

In December 2011, we expanded the existing drug development partnership with BMS to focus on the co-development of BMS's cardiovascular disease candidate, BMS-795311, a preclinical-stage small molecule inhibitor of the cholesteryl ester transfer protein. Under the terms of the co-development agreement, we are expected to receive an exclusive license to develop and market the drug in China while BMS will retain exclusive rights in all other markets.

**Product Candidates**

We are developing a number of new pharmaceuticals through our in-house expertise and through joint research and development efforts with universities and research institutions in China.

As of March 31, 2013, we had over 11 product candidates in various stages of development. Details of the product candidates that we believe have the highest potential for commercialization in the next two or three years are summarized below:

Product Candidate	Therapeutic Effects and Scope of Applications	Status	Patentable	Potential Monitoring Period
Bendamustine Hydrochloride for Injection	Treatment of chronic lymphocytic leukemias (CLL), Indolent B cell non-Hodgkin's lymphoma (NHL)	Phase III Clinical Study	No	4 years

***Bendamustine Hydrochloride for Injection.*** Bendamustine Hydrochloride, an alkylating agent that also has characteristics of antimetabolites, is a nitrogen mustard class of anticancer drugs used for the treatment of chronic lymphocytic leukemias, Indolent B cell non-Hodgkin's lymphoma and other diseases. We are conducting Phase III clinical study for this product candidate and we plan to subsequently submit the New Drug Application to CFDA in 2013.

**Intellectual Property**

We are committed to the development and protection of our intellectual property portfolio. We rely primarily on a combination of patent, trademark and trade secret protections, as well as employee and third party confidentiality agreements to safeguard our intellectual property. We own and have applied for patents to protect the technologies, inventions and improvements that we believe are significant to our business. As of March 31, 2013, we hold 66 patents in China, three patents in the United States, two patents in Australia, three patents in Europe, and one patent in Canada. We also hold one utility model patents and 27 design patents. In addition, we have 95 pending patent applications in China and 18 pending patent applications filed under the Patent Cooperation Treaty, which provides a unified procedure for filing patent applications to protect inventions internationally.

Table of Contents

The validity period for our utility model patents and design patents are both 10 years and the validity period for our patents is 20 years, starting from the date the application was filed. All of these patents were issued in China. As with patent rights in most other jurisdictions, a patent holder in China enjoys the exclusive right to exclude others from using, licensing and otherwise exploiting the patent in China. However, there is no assurance that our patents will not be challenged in China, which could be costly to defend and could divert our management from their normal responsibilities. See Item 3. Key Information D. Risk Factors Risks Related to Our Company 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 and Litigation to protect our intellectual property rights or defend against third-party allegations of infringement may be costly. In addition, if such challenge is successful, it could result in an adverse effect on our business.

We rely on trademarks to protect our branded generic pharmaceuticals, which constitute a significant portion of our sales and are not protected by patents. As of March 31, 2013, we maintained 741 trademark registrations in China, including the Chinese characters for Bicun, Zailin, Yingtaiqing, Anqi and Biqi. We have also applied for an additional 26 trademarks. 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 the State Administration for Industry and Commerce. Trademark registration is valid for ten years, starting from the day the registration is approved. If we believe that a third party has infringed upon the exclusive right of our registered trademark, we may, through appropriate administrative and civil procedures prescribed, institute proceedings to request the relevant authority for an injunction or to resolve the infringement through consultation. The relevant authority can also impose fines, confiscate or destroy the infringing products or equipment used to manufacture the infringing products.

We believe that certain of our trademarks are well-recognized in China among healthcare professionals, pharmacists and patients. For example, our brand name Zailin was recognized as a China Well-Known Trademark in 2004 and our brand name Yingtaiqing was named a China Well-Known Trademark in 2008. Under PRC law, if we believe such well-known trademark is registered by a third party as its company name, and that such registration might result in confusion to the general public, we may also apply to the relevant administrative authority for an injunction prohibiting such use and to compel the third party to cancel its registration. As our brand names are becoming more recognized in the pharmaceutical market in China, we are devoting additional resources to increasing and enforcing our trademark rights, which is critical to our overall branding strategy and reputation.

Some elements of our pharmaceutical composition, formulation, delivery as well as manufacturing methods or processes involve unpatented, proprietary technology, processes, know-how or data. With respect to such proprietary know-how that is not patentable and processes for which patents are difficult to enforce, we rely on trade secret protection and confidentiality agreements in order to safeguard our interests. All of our research and development personnel have entered into confidentiality, non-competition and proprietary information agreements with us. These agreements address issues involving the protection of our intellectual property and require such employees to assign to us all of their inventions, designs and technologies that they may develop during their periods of employment with us. In addition, there is a strict segregation of duties among personnel involved in different stages of our production process. This serves to reduce the risk of any single staff member obtaining the technical know-how relating to the entire production process. We also take other precautions, such as internal document controls and network assurance procedures, including the use of a separate dedicated server for technical data.

If our trademarks are challenged, our brand name is damaged and/or our trade secrets become known by our competitors, there could be an adverse effect on our business. See Item 3. Key Information D. Risk Factors Risks Related to Our Company 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.

Table of Contents*D. Trend Information*

Please refer to *A. Operating Results Overview* for a discussion of the most significant recent trends in our production, sales, costs and selling prices. In addition, please also refer to discussions included in this Item for a discussion of known trends, uncertainties, demands, commitments or events that we believe are reasonably likely to have a material effect on our net operating revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial condition.

*E. Off-Balance Sheet Arrangements*

We do not have any outstanding interest rate swap transactions or foreign currency forward contracts. We do not engage in trading activities involving non-exchange traded contracts. In the ordinary course of our business, we do not enter into transactions involving, or otherwise form relationships with, unconsolidated entities or financial partnerships that are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

*F. Tabular Disclosure of Contractual Obligations*

The following table sets forth our contractual obligations at December 31, 2012:

	<b>Contractual Obligations</b>				
	<b>Less than 1 Year RMB</b>	<b>1-3 Years RMB</b>	<b>3-5 Years RMB (in thousands)</b>	<b>More than 5 Years RMB</b>	<b>Total RMB</b>
Short-term borrowings	675,779				675,779
Long-term borrowings		2,000			2,000
Interest payments	25,862				25,862
Liabilities for uncertain tax position	10,462	14,195			24,657
Payable for intangible assets acquisition(1)		8,000			8,000
Operating lease commitments	1,792	601	6	12	2,411
Research and development projects	22,776				22,776
Capital commitments	863				863
<b>Total</b>	<b>737,534</b>	<b>24,796</b>	<b>6</b>	<b>12</b>	<b>762,348</b>

(1) The payment term is subject to the annual sales of Iremod in the coming years. The years of contractual obligation are estimated based on management's sales forecast.

*G. Safe Harbor*

This annual report contains forward-looking statements that relate to our current expectations and views of future events. The forward-looking statements relate to events that involve known and unknown risks, uncertainties and other factors, including those listed under Item 3. Key Information D. Risk Factors, which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.



Table of Contents

In some cases, these forward-looking statements can be identified by words or phrases such as may, will, expect, anticipate, aim, estimate, intend, plan, believe, potential, continue, is/are likely to or other similar expressions. We have based these forward-looking statements on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, among other things, statements relating to:

- our anticipated growth strategies;
  
- our future business development, results of operations and financial condition;
  
- market acceptance of our products and product candidates;
  
- our ability to effectively protect our intellectual property and trade secrets and not infringe on the intellectual property and trade secrets of others;
  
- the sufficiency of our existing and future intellectual property right protections;
  
- our ability to obtain regulatory approval for products that we develop;
  
- our ability to successfully develop and improve products;
  
- changes in the healthcare industry in China, including increased availability of funding for medical insurance coverage and the inclusion of additional medicines in the Essential Drug List and Reimbursement List;
  
- our ability to manage our expansion of operations;
  
- environmental compliance costs and liabilities;

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- competition from other manufacturers of pharmaceutical products;
- the expected growth for the pharmaceutical industry in China;
- our ability to obtain permits and licenses to carry on our business; and
- fluctuations in general economic and business conditions in China.

The forward-looking statements made in this annual report relate only to events or information as of the date on which the statements are made in this annual report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this annual report on Form 20-F and the documents that we reference in this annual report and have filed as exhibits to the registration statement, of which this annual report is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

Table of Contents**Item 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES***A. Directors and Senior Management***Directors and Executive Officers**

The following table sets forth information regarding our directors and executive officers as of the date of this annual report.

<b>Name</b>	<b>Age</b>	<b>Position/Title</b>
Jinsheng Ren	51	Chairman of the board of directors
Hongquan Liu	54	Chief executive officer and director
Guoqiang Lin(1) (2) (3)	70	Independent director
Alan Au(1)(3)	41	Independent director
John Huan Zhao (2)	50	Director
Yehong Zhang	50	Chief Executive Officer of Simcere MSD (Shanghai) Pharmaceutical Co., Ltd.
Jindong Zhou	51	Executive vice president
Xiaojin Yin	54	Senior vice president of research and development
Yushan Wan	43	Acting chief financial officer
Quanfu Feng	48	Vice president
Jialun Tian	48	Vice president
Peng Wang	54	Chief scientific officer
Jie Liu D Elia	39	Vice president
Haibo Qian	50	Vice president and Secretary to the board of directors

---

(1) Audit committee members.

(2) Compensation committee members.

(3) Corporate governance and nominating committee members.

*Mr. Jinsheng Ren* is our founder, chairman of our board of directors. Prior to founding our company in March 1995, he was a department manager at Jiangsu Pharmaceutical Industries Co., Ltd. from 1992 to 1995. From 1982 to 1992, he was the vice general manager of Qidong Gaitianli Medicines Co., Ltd. Mr. Ren graduated from the Nanjing University of Traditional Chinese Medicine in 1982 majoring in Chinese Medicine, and received a master's degree in Economics from University of Macquarie in Australia in 2003. He is currently a guest professor at the Nanjing University of Traditional Chinese Medicine and an adjunct professor of Northwest University in China.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

*Mr. Hongquan Liu* is our chief executive officer and director. Mr. Liu was the managing director of Sino-Swed Pharmaceutical Corp. Ltd since 2000. In 2000, he served as the general manager of Wuxi Pharmaceutical Company of Jiangsu CTD Import & Export Co., Ltd. From 1998 to 2000, he was the managing director of Pharmacia Corporation. From 1996 to 1998, he was the chief marketing and business officer of Pharmacia Corporation. From 1995 to 1996, he was the chief financial officer of Pharmacia Corporation. From 1992 to 1995, he was a general manager of Sino-Swed Pharmaceutical Corp. Ltd. Mr. Liu received a bachelor's degree from Shanxi College of Finance and Economics in 1983 and an EMBA degree from China Europe International Business School in 2000.

*Professor Guoqiang Lin*, an organic chemist, is an independent director of our company. Prof. Lin is the chairman of our corporate governance and nominating committee, and a member of our audit committee and compensation committee. Prof. Lin received a bachelor's degree in Chemistry from Shanghai University of Science and Technology (now Shanghai University) in 1964. He entered the postgraduate program of Shanghai Institute of Organic Chemistry of the Chinese Academy of Sciences in 1964 and graduated from it in 1968. Prof. Lin is a researcher for the Shanghai Institute of Organic Chemistry of the Chinese Academy of Sciences since 1989. He has worked as a visiting scholar in Royal Institute of Sweden, Pittsburgh University of U.S. and SmithKline Pharmaceuticals.

*Mr. Alan Au* is our independent director and chairman of our audit committee and a member of our corporate governance and nominating committee. He is a Certified Public Accountant in the U.S. and holds the Chartered Financial Analyst designation. He also serves on the Assessment Panel of the Small Entrepreneur Research Assistance Program (SERAP) of the Hong Kong SAR Government. Mr. Au was the head of healthcare for Deutsche Bank's Asia Investment Banking Group from 2011 to 2012. Prior to that, he was a director at JAFCO Asia Investment Group, responsible for healthcare investments in China from 2008 to 2011, and a director at Morningside Group responsible for healthcare investments in Asia from 2000 to 2005. From 1995 to 1999, Mr. Au worked at KPMG and KPMG Corporate Finance Ltd., responsible for regional M&A transactions and financial advisory services. Mr. Au received his Bachelor's degree in Psychology from the Chinese University of Hong Kong in 1995, and a Master's degree in Management from Columbia University in 2007.

Table of Contents

*Mr. John Huan Zhao* is a director of our company and the chairman of our compensation committee. Mr. Zhao also serves as the chief executive officer of Hony Capital Limited and an Executive Vice President and an executive director at Legend Holdings Limited. Prior to joining Hony Capital Limited and Legend Holdings Limited in 2003, Mr. Zhao was the advisor to the chief executive officer of UTStarcom Inc. and Lenovo Group Ltd. from 2002 to 2003. From 2001 to 2002, he was a managing director of eGarden Ventures, Ltd. Prior to that, he was the chairman, president and chief executive officer of Infolio, the chairman, president and chief executive officer of Vadem Ltd. and senior manager of U.S. Robotics, Inc. and Shure Brothers, Inc. Mr. Zhao received a bachelor's degree in Physics from Nanjing University in 1984, dual master's degrees in Electrical Engineering and Physics from Northern Illinois University in 1990, and a MBA degree from the Kellogg School of Management at Northwestern University in 1996.

*Dr. Yehong Zhang* currently serves as the chief executive officer of Simcere MSD (Shanghai) Pharmaceutical Co. Ltd, the newly established joint venture between Simcere and Merck & Co., Inc. (NYSE: MRK), effective from October 8, 2012. Before that, Dr. Zhang was president of Simcere Pharmaceutical Group. He has over 18 years of experience in the healthcare industry, including serving as a senior healthcare practice leader in McKinsey's China office focusing on systemic issues impacting the healthcare industry. Dr. Zhang worked for over 12 years at Merck Sharp & Dohme in the United States, China, and other regions. During his tenure at Merck Sharp & Dohme, he held positions of responsibility in product manufacturing, supply chain operations and business development. From 2007 to 2008, he served as president of Merck in China. He was also the Greater China Country Managing Director for IMS from 2004-2007. Dr. Zhang received an MBA degree from the Wharton School of the University of Pennsylvania, a Ph.D. in engineering from the University of Pennsylvania and a bachelor's degree from Harvard University.

*Mr. Jindong Zhou* is our executive vice president. Mr. Zhou joined our company in 1996 and has held various positions, including the general manager of Nanjing Simcere Pharmaceutical Co., Ltd., Simcere Dongyuan Pharmaceutical Co., Ltd. and Simcere (Hainan) Pharmaceutical Co., Ltd. Mr. Zhou graduated from the Nanjing University of Traditional Chinese Medicine majoring in Chinese Medicine in 1982, and he received a master's degree in Economics from University of Macquarie in Australia in 2008.

*Mr. Xiaojin Yin* is our senior vice president in charge of research and development. From 2003 to 2006, Mr. Yin was the general manager of Simcere Research. From 2000 to 2003, he was the general manager assistant of Simcere Pharmaceutical Co., Ltd. and manager of Simcere Research. From 1992 to 2000, he was the head of the medical research department of the China Pharmaceutical University in Nanjing. From 1991 to 1992, Mr. Yin was the general manager of the medicine production facility at China Pharmaceutical University. Mr. Yin received a bachelor's degree in Medical Sciences from China Pharmaceutical University in 1982 and a master's degree in Industrial Engineering from the Nanjing University of Science and Technology in 2001.

*Mr. Yushan Wan* is our acting chief financial officer. Mr. Wan joined our company in 2000 and has been serving as our corporate controller since 2007. He was appointed as our acting chief financial officer in January 2011. Mr. Wan has a bachelor's degree in biochemistry and a master's degree in accounting from Nanjing University and is a Chinese Certified Public Accountant.

*Mr. Quanfu Feng* is our vice president. Mr. Feng joined us in 1995 and has been working in a number of departments within our company, including the marketing and advertising department, the human resources department, the corporate culture department and the general manager's office. Prior to being promoted to his current position, Mr. Feng served in various positions, including as regional manager and local manager, director of the president's office assistant to the president, deputy general manager of Jiangsu Simcere, and general manager of our south China division and our Jiangsu division. Mr. Feng obtained his bachelor's degree in pedagogy from East China Normal University and a master's degree in medicine from Nanjing University of Chinese Medicine. Mr. Feng is also currently an adjunct professor at Nanjing University of Chinese Medicine.



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

*Mr. Jialun Tian* is our vice president of hospital sales. From 2000 to 2008, Mr. Tian held various positions in our company, including a regional manager, a commercial sales director and the general manager of commercial sales department, the deputy general manager of Jiangsu Simcere, the general manager of purchasing department, the South China division general manager, and the assistant to our CEO. Prior to joining Simcere, Mr. Tian was the manager of financial department of Nanjing Kokhai Biotechnical Co., Ltd., the operational deputy general manager of Nanjing Luhe Pharmaceutical Factory, and the manager of financial department of Nanjing C&O Pharmaceutical Co. Ltd. Mr. Tian graduated from the accounting department of Jiangsu Radio and TV University. He received an MBA from Tsinghua University in 2002 and an MBA from Hong Kong Baptist University in 2008.

*Mr. Peng Wang* is our chief scientific officer. He has over 20-year experience in pharmaceutical research and development. Prior to joining us in 2009, he was a vice president and standing executive committee member of WuXi AppTec. From 1990 to 2008, he worked with Schering-Plough as the co-chair of the discovery team and a member of the early development team. Mr. Wang graduated from the medicinal chemistry department of China Pharmaceutical University, and received a Ph. D from the pharmaceutical science department of the University of Tokyo in 1990.

*Dr. Jie Liu D Elia* is our vice president of business development and corporate communications, and the President of Simcere of America. She is based in Seattle, Washington and Princeton, New Jersey. Dr. Jie Liu D Elia has over twelve years of experience in the pharmaceutical industry. She joined Simcere from Allozyne, Inc., a Seattle-based biotech company, where she served as its Vice President of Business Development and Licensing. Prior to Allozyne, Dr. Jie Liu D Elia spent two years in Shanghai and served as the head of business development and strategic planning at AstraZeneca China, where she directed the licensing initiatives and the planning efforts for AstraZenecas late-stage products in the China market. Previously, Dr. Jie Liu D Elia worked as a Consultant at the New York office of the Boston Consulting Group, advising Fortune 500 companies on strategy and operational issues. Dr. D Elia holds an MBA from Columbia Business School and a Ph.D. in Pharmaceutical Sciences from the University of Texas at Austin.

*Dr. Haibo Qian* is the secretary to our board of directors and our company secretary. From 1993 to the present, he has held various roles in our company, including chief inspector, special assistant to the chief executive officer, market strategy department manager, and department general manager. In 2005, he was also the special assistant to the chief executive officer of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. From 1986 to 1993, he was the director at the Health Economics Department of Nanjing Medical University. He received a bachelor's degree in Law from Nanjing Normal University in 1986, graduated from Shanghai Medical University in 1993 majoring in Health Economics, received a MBA from Nanjing University in 2002 and received a Ph.D. degree in Management and Social Medicine from the China Pharmaceutical University in 2007. Dr. Qian is a certified pharmacist.

The address of our directors and executive officers is c/o Simcere Pharmaceutical Group, No. 699-18 Xuan Wu Avenue, Xuan Wu District, and Nanjing, Jiangsu Province 210042, the People's Republic of China.

### *B. Compensation*

#### **Compensation of Directors and Executive Officers**

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

In 2012, the aggregate cash compensation to our executive officers, including all the directors, was RMB16.99 million (\$2.7 million). For share-based compensation, see 2006 Share Incentive Plan.



Table of Contents

**2006 Share Incentive Plan**

The 2006 share incentive plan was adopted by our shareholders on November 13, 2006. Our share incentive plan provides for the grant of options, share appreciation rights, and other share-based awards such as restricted shares, referred to as awards. The purpose of the plan is to aid us in recruiting and retaining key employees, directors or consultants of outstanding ability and to motivate such employees, directors or consultants to exert their best efforts on behalf of our company by providing incentives through the granting of awards. Our board of directors believes that our company's long-term success is dependent upon our ability to attract and retain superior individuals who, by virtue of their ability, experience and qualifications, make important contributions to our business.

*Termination of Awards.* Options and restricted shares shall have specified terms set forth in an award agreement. The compensation committee will determine in the relevant award agreement whether options granted under the award agreement will be exercisable following the recipient's termination of services with us. If the options are not exercised or purchased on the last day of the period of exercise, they will terminate.

*Administration.* Our 2006 share incentive plan is administered by the compensation committee of our board of directors. The committee is authorized to interpret the plan, to establish, amend and rescind any rules and regulations relating to the plan, and to make any other determinations that it deems necessary or desirable for the administration of the plan. The committee will determine the provisions, terms and conditions of each award, including, but not limited to, the exercise price for an option, vesting schedule of options and restricted shares, forfeiture provisions, form of payment of exercise price and other applicable terms.

*Option Exercise.* The term of options granted under the 2006 share incentive plan may not exceed six years from the date of grant. The consideration to be paid for our ordinary shares upon exercise of an option or purchase of shares underlying the option may include cash, check or other cash-equivalent, ordinary shares, consideration received by us in a cashless exercise, or any combination of the foregoing methods of payment.

*Third-party Acquisition.* If a third-party acquires us through the purchase of all or substantially all of our assets, a merger or other business combination, the compensation committee may decide that all outstanding awards that are unexercisable or otherwise unvested or subject to lapse restrictions will automatically be deemed exercisable or otherwise vested or no longer subject to lapse restrictions, as the case may be, as of immediately prior to such acquisition. The compensation committee may also, in its sole discretion, decide to cancel such awards for fair value, provide for the issuance of substitute awards that will substantially preserve the otherwise applicable terms of any affected awards previously granted, or provide that affected options will be exercisable for a period of at least 15 days prior to the acquisition but not thereafter.

*Amendment and Termination of Plan.* Our board of directors may at any time amend, alter or discontinue our 2006 share incentive plan. Amendments or alterations to our 2006 share incentive plan are subject to shareholder approval if they increase the total number of shares reserved for the purposes of the plan or change the maximum number of shares for which awards may be granted to any participant, or if shareholder approval is required by law or by stock exchange rules or regulations. Any amendment, alteration or termination of our 2006 share incentive plan must not adversely affect awards already granted without written consent of the recipient of such awards. Unless terminated earlier, our 2006 share incentive plan shall continue in effect for a term of ten years from the date of adoption.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Our board of directors and shareholders authorized the issuance of up to 12,000,000 ordinary shares upon exercise of awards granted under our 2006 share incentive plan. On November 15, 2006, we granted 10,000,000 options to our senior management and key employees with an exercise price of \$4.20 per share. On March 29, 2007, we granted 1,045,000 options to our independent directors and certain of our employees with an exercise price equal to \$6.75. On May 5, 2008, we granted 400,000 options to one of our officers with an exercise price equal to \$6.755. On December 24, 2008, we also granted 100,000 options to one of our officers with an exercise price equal to \$3.445. On September 1, 2010, we granted 978,000 options to our officers and key employees with an exercise price of \$4.545 per share. On April 15, 2009, our compensation committee approved a share option exchange program that offered our eligible directors, employees and consultants the right to exchange vested and unvested outstanding share options to purchase our ordinary shares granted under the 2006 Share Incentive Plan for our restricted shares. The exchange ratio was determined based on the fair value of replacement restricted shares so that the fair value of the replacement restricted shares to be issued upon exchange would be approximately equivalent to the fair value of the share options surrendered by an individual. In addition, these replacement restricted shares are subject to substantially the same vesting schedule as the options that were validly tendered in the exchange offer. A total of 154 directors and employees accepted the offer, and tendered options to purchase an aggregate of 9,802,400 ordinary shares in exchange for 1,833,990 vested shares and 2,916,028 non-vested shares, which were granted on May 7, 2009. The exchange of the share option awards for restricted shares was accounted for as a modification of awards which involves a cancellation of the original award and an issuance of a new award. The effect of this award modification on share-based compensation expense over the remaining requisite service period was insignificant. This exchange program is expected to provide additional incentive and retention value.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

On October 14, 2009 and December 4, 2009, we granted 200,000 and 40,000 restricted shares to our officers and key employees under our 2006 share incentive plan, respectively.

During 2010, we granted 870,000 restricted shares in total to our officers and key employees under our 2006 share incentive plan, including 480,000 restricted shares granted on March 9, 2010 to our independent directors and president.

During 2011, we granted 364,000 restricted shares to our officers and key employees under our 2006 share incentive plan.

During 2012, we granted 4,140,000 restricted shares to our directors and key employees under our 2006 share incentive plan.

The restricted shares to our directors, officers and employees are listed below.

Name	Number of Restricted Shares Granted	Date of Grant of Restricted Shares	Date of Grant of Cancelled Option	End of Vesting Period
Jinsheng Ren	2,665,998	May 7, 2009	November 15, 2006	November 14, 2011
	4,000,000	September 11, 2012	n/a	September 10, 2017
Hongquan Liu	12,018	May 7, 2009	March 29, 2007	March 28, 2012
	60,000	March 9, 2010	n/a	March 8, 2012
Yehong Zhang	*(1)	March 9, 2010	n/a	March 9, 2013
Yushan Wan	*(1)	May 7, 2009	November 15, 2006	November 14, 2011
Jindong Zhou	*(1)	May 7, 2009	November 15, 2006	November 14, 2011
Xiaojin Yin	*(1)	May 7, 2009	November 15, 2006	November 14, 2011
Jialun Tian	*(1)	May 7, 2009	November 15, 2006	November 14, 2011
Quanfu Feng	*(1)	May 7, 2009	November 15, 2006	November 14, 2011
Peng Wang	*(1)	October 14, 2009	n/a	October 13, 2014
Jie Liu D Elia	*(1)	October 14, 2009	n/a	October 13, 2014
Guoqiang Lin	*(1)	May 7, 2009	March 29, 2007	March 28, 2012
	*(1)	March 9, 2010	n/a	March 8, 2012
	*(1)	September 11, 2012	n/a	September 10, 2017
John Huan Zhao	*(1)	September 11, 2012	n/a	September 10, 2017
Other employees as a group(2)	1,406,968	May 7, 2009	November 15, 2006	November 14, 2011
Other employees as a group(2)	28,048	May 7, 2009	March 29, 2007	March 28, 2012
Other employees as a group(2)	188,414	May 7, 2009	May 5, 2008	March 8, 2013
Other employees as a group(2)	63,372	May 7, 2009	December 24, 2008	August 31, 2013
Other employees as a group(2)	40,000	October 14, 2009	n/a	October 13, 2014
Other employees as a group(2)	40,000	December 4, 2009	n/a	December 3, 2014
Other employees as a group(2)	10,000	January 10, 2010	n/a	January 9, 2015
Other employees as a group(2)	40,000	February 26, 2010	n/a	February 25, 2015
Other employees as a group(2)	100,000	April 16, 2010	n/a	April 15, 2015
Other employees as a group(2)	40,000	July 1, 2010	n/a	June 30, 2015
Other employees as a group(2)	40,000	July 26, 2010	n/a	July 25, 2015
Other employees as a group(2)	20,000	August 16, 2010	n/a	August 15, 2015

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Other employees as a group(2)	40,000	September 1, 2010	n/a	August 31, 2015
Other employees as a group(2)	40,000	October 1, 2010	n/a	September 30, 2015
Other employees as a group(2)	20,000	October 18, 2010	n/a	October 17, 2015
Other employees as a group(2)	30,000	November 1, 2010	n/a	October 31, 2013
Other employees as a group(2)	10,000	November 17, 2010	n/a	November 16, 2013
Other employees as a group(2)	180,000	February 12, 2011	n/a	February 11, 2014
Other employees as a group(2)	7,600	February 28, 2011	n/a	February 27, 2014
Other employees as a group(2)	40,000	March 1, 2011	n/a	February 29, 2016
Other employees as a group(2)	30,000	April 1, 2011	n/a	March 31, 2014
Other employees as a group(2)	7,600	May 16, 2011	n/a	May 15, 2014
Other employees as a group(2)	8,800	July 1, 2011	n/a	June 30, 2014
Other employees as a group(2)	20,000	July 1, 2011	n/a	June 30, 2016
Other employees as a group(2)	30,000	August 1, 2011	n/a	July 31, 2014
Other employees as a group(2)	40,000	September 21, 2011	n/a	September 20, 2016
Other employees as a group(2)	40,000	March 1, 2012	n/a	February 28, 2017

Table of Contents

The options to our officers and employees as listed below:

Name	Number of Ordinary Underlying Options Granted	Exercise Price (\$/Share)	Date of Grant	Date of Expiration
Yushan Wan	*(1) \$	4.545	September 1, 2010	August 31, 2015
Jialun Tian	*(1) \$	4.545	September 1, 2010	August 31, 2015
Quanfu Feng	*(1) \$	4.545	September 1, 2010	August 31, 2015
Other employees as a group(2)	966,000 \$	4.545	September 1, 2010	August 31, 2015

(1) Beneficially own less than 1.0% of our outstanding ordinary shares.

(2) None of these employees is our director or executive officer.

## 2008 Share Incentive Plan

The 2008 share incentive plan was adopted by our shareholders on July 31, 2008. Our share incentive plan provides for the grant of options, share appreciation rights, and other share-based awards such as restricted shares, referred to as awards. The purpose of the plan is to aid us in recruiting and retaining key employees, directors or consultants of outstanding ability and to motivate such employees, directors or consultants to exert their best efforts on behalf of our company by providing incentives through the granting of awards. Our board of directors believes that our company's long-term success is dependent upon our ability to attract and retain superior individuals who, by virtue of their ability, experience and qualifications, make important contributions to our business.

*Termination of Awards.* Options and restricted shares shall have specified terms set forth in an award agreement. The compensation committee will determine in the relevant award agreement whether options granted under the award agreement will be exercisable following the recipient's termination of services with us. If the options are not exercised or purchased on the last day of the period of exercise, they will terminate.

*Administration.* Our 2008 share incentive plan is administered by the compensation committee of our board of directors. The committee is authorized to interpret the plan, to establish, amend and rescind any rules and regulations relating to the plan, and to make any other determinations that it deems necessary or desirable for the administration of the plan. The committee will determine the provisions, terms and conditions of each award, including, but not limited to, the exercise price for an option, vesting schedule of options and restricted shares, forfeiture provisions, form of payment of exercise price and other applicable terms.

Table of Contents

*Option Exercise* . The term of options granted under the 2008 share incentive plan may not exceed ten years from the date of grant. The consideration to be paid for our ordinary shares upon exercise of an option or purchase of shares underlying the option may include cash, check or other cash-equivalent, ordinary shares, consideration received by us in a cashless exercise, or any combination of the foregoing methods of payment.

*Third-party Acquisition* . If a third-party acquires us through the purchase of all or substantially all of our assets, a merger or other business combination, the compensation committee may decide that all outstanding awards that are unexercisable or otherwise unvested or subject to lapse restrictions will automatically be deemed exercisable or otherwise vested or no longer subject to lapse restrictions, as the case may be, as of immediately prior to such acquisition. The compensation committee may also, in its sole discretion, decide to cancel such awards for fair value, provide for the issuance of substitute awards that will substantially preserve the otherwise applicable terms of any affected awards previously granted, or provide that affected options will be exercisable for a period of at least 15 days prior to the acquisition but not thereafter.

*Amendment and Termination of Plan*. Our board of directors may at any time amend, alter or discontinue our 2008 share incentive plan. Amendments or alterations to our 2008 share incentive plan are subject to shareholder approval if they increase the total number of shares reserved for the purposes of the plan or change the maximum number of shares for which awards may be granted to any participant, or if shareholder approval is required by law or by stock exchange rules or regulations. Any amendment, alteration or termination of our 2008 share incentive plan must not adversely affect awards already granted without written consent of the recipient of such awards. Unless terminated earlier, our 2008 share incentive plan shall continue in effect for a term of ten years from the date of adoption.

Our board of directors and shareholders authorized the issuance of up to 6,250,000 ordinary shares upon exercise of awards granted under our 2008 share incentive plan. During 2012, we granted 2,000,000 restricted shares to one of our directors under the 2008 share incentive plan.

The restricted shares to our directors, officers and employees are listed below.

Name	Number of Restricted Shares Granted	Date of Grant of Restricted Shares	Date of Grant of Cancelled Option	End of Vesting Period
Hongquan Liu	2,000,000	October 8, 2012	n/a	October 7, 2017

**Employee Pension and Other Retirement Benefits**

Pursuant to the relevant PRC regulations, we are required to make contributions for each employee at a rate of 20% of a standard salary base as determined by the local social security bureau to a defined contribution retirement scheme organized by the local social security bureau. Contributions of RMB24.2 million (\$3.9 million) were paid in 2012, which were charged to expense. We have no other obligation to make payments in respect of retirement benefits of our employees.



Table of Contents

C. *Board Practices*

**Duties of Directors**

Under Cayman Islands law, our directors have a fiduciary duty to act honestly, in good faith and with a view to our best interests. Our directors also have a duty to exercise the skill they actually possess and such care and diligence that a reasonably prudent person would exercise in comparable circumstances. In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of association, as amended and re-stated from time to time. Directors may be liable for any loss suffered by us as a result of a breach of their fiduciary duties.

The functions and powers of our board of directors include, among others:

- convening shareholders annual general meetings and reporting its work to shareholders at such meetings;
- declaring dividends and distributions;
- appointing officers and determining the term of office of officers;
- exercising the borrowing powers of our company and mortgaging the property of our company; and
- approving the transfer of shares of our company, including the registering of such shares in our share register.

Our board of directors has established an audit committee, a compensation committee and a corporate governance and nominating committee upon completion of our initial public offering in April 2007.

*Audit Committee*



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Our audit committee consists of Messrs. Alan Au and Guoqiang Lin, each of whom satisfies the requirements of New York Stock Exchange Listed Company Manual, or NYSE Manual, Section 303A. Alan Au will be the chairman of our audit committee and meets the criteria of an audit committee financial expert as set forth under the applicable rules of the SEC. Both members of the audit committee will be an independent director within the meaning of NYSE Manual Section 303A(2) and will meet the criteria for independent set forth in Section 10A(m)(3) of the United States Securities Exchange Act of 1934, as amended, or the Exchange Act. The audit committee oversees our accounting and financial reporting processes and the audits of the financial statements of our company. The audit committee is responsible for, among other things:

- selecting our independent registered public accounting firm and pre-approving all auditing and non-auditing services permitted to be performed by our independent registered public accounting firm;
- reviewing with our independent registered public accounting firm any audit problems or difficulties and management's response;
- reviewing and approving all proposed related-party transactions, as defined in Item 404 of Regulation S-K under the Securities Act;
- discussing the annual audited financial statements with management and our independent registered public accounting firm;
- reviewing major issues as to the adequacy of our internal controls and any special audit steps adopted in light of significant control deficiencies;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- such other matters that are specifically delegated to our audit committee by our board of directors from time to time; and
- meeting separately and periodically with management and our internal auditor and independent registered public accounting firm.

Table of Contents

*Compensation Committee*

Our compensation committee consists of Messrs. John Huan Zhao and Guoqiang Lin. Mr. Guoqiang Lin will be an independent director within the meaning of NYSE Manual Section 303A(2). Our compensation committee assists the board in reviewing and approving the compensation structure of our directors and executive officers, including all forms of compensation to be provided to our directors and executive officers. Members of the compensation committee are not prohibited from direct involvement in determining their own compensation. Our chief executive officer may not be present at any committee meeting during which his compensation is deliberated. The compensation committee is responsible for, among other things:

- approving and overseeing the compensation package for our executive officers;
- reviewing and making recommendations to the board with respect to the compensation of our directors; and
- reviewing periodically any long-term incentive compensation or equity plans, programs or similar arrangements, annual bonuses, employee pension and welfare benefit plans and granting our executive officers awards under such plans.

*Corporate Governance and Nominating Committee*

Our corporate governance and nominating committee consists of Messrs. Guoqiang Lin and Alan Au, both of whom will be independent directors within the meaning of NYSE Manual Section 303A(2). The corporate governance and nominating committee assists the board of directors in identifying individuals qualified to become our directors and in determining the composition of the board and its committees. The corporate governance and nominating committee is responsible for, among other things:

- identifying and recommending to the board nominees for election or re-election to the board, or for appointment to fill any vacancy;
- reviewing annually with the board the current composition of the board in light of the characteristics of independence, age, skills, experience and availability of service to us;
- advising the board periodically with respect to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to the board on all matters of corporate governance and on any corrective action to be taken; and

- monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance.

Table of Contents

***Terms of Directors and Executive Officers***

Our executive officers are elected by and serve at the discretion of the board of directors. Our directors are not subject to a term of office and hold office until such time as they resign or are removed from office without cause by special resolution or the unanimous written resolution of all shareholders or with cause by ordinary resolution or the unanimous written resolutions of all shareholders. A director will be removed from office automatically if, among other things, the director (i) becomes bankrupt or makes any arrangement or composition with his creditors; or (ii) dies or is found by our company to be or becomes of unsound mind.

***Employment Agreements***

We have entered into employment agreements with all of our executive officers. Under these agreements, each of our executive officers is employed for a specified time period. We may terminate his or her employment for cause at any time, with prior written notice, for certain acts of the employee, including but not limited to a conviction to a felony, or willful gross misconduct by the employee in connection with his employment, and in each case if such acts have resulted in material and demonstrable financial harm to us. An executive officer may, with prior written notice, terminate his or her employment at any time for any material breach of the employment agreement by us that is not remedied promptly after receiving the remedy request from the employee. Furthermore, either party may terminate the employment agreement at any time without cause upon advance written notice to the other party. Upon termination, the employee is generally entitled to a severance pay of at least one month's salary.

Each executive officer has agreed to hold, both during and subsequent to the terms of his or her agreement, in confidence and not to use, except in pursuance of his or her duties in connection with the employment, any of our confidential information, technological secrets, commercial secrets and know-how. Our executive officers have also agreed to disclose to us all inventions, designs and techniques resulted from work performed by them, and to assign us all right, title and interest of such inventions, designs and techniques.

***Interested Transactions***

A director may vote in respect of any contract or transaction in which he or she is interested, provided that the nature of the interest of any directors in such contract or transaction is disclosed by him or her at or prior to its consideration and any vote in that matter.

***Remuneration and Borrowing***

The directors may determine remuneration to be paid to the directors. The compensation committee assists the directors in reviewing and approving the compensation structure for the directors. The directors may exercise all the powers of the company to borrow money and to mortgage or charge its undertaking, property and uncalled capital, and to issue debentures or other securities whether outright or as security for any debt obligations of our company or of any third party.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### D. *Employees*

We had 4,046, 4,334 and 4,349 employees as of December 31, 2010, 2011 and 2012, respectively. The following table sets forth the number of our employees for each of our areas of operation and as a percentage of our total workforce as of December 31, 2012:

	<b>Number of Employees</b>	<b>Percentage of total</b>
Marketing and brand management	2,042	47.0%
Manufacturing and quality control	1,341	30.8%
General and administration	604	13.9%
Research and development	362	8.3%
Total	4,349	100%

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

We are required under PRC law to make contributions to our employee benefit plans based on specified percentages of the salaries, bonuses, housing funds and certain allowances of our employees, up to a maximum amount specified by the respective local government authorities where we operate our businesses, in respect of the retired benefits. The total amount of contributions we made to employee benefit plans in 2010, 2011 and 2012, was RMB15.6 million, RMB22.7 million and RMB24.2 million (\$3.9 million) respectively.

Our employees are not covered by any collective bargaining agreement. We believe that we have a good relationship with our employees.

### *E. Share Ownership*

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of April 19, 2013, the latest practicable date, by:

- each of our directors and executive officers; and
- each person known to us to own beneficially more than 5.0% of our ordinary shares.

	Shares Beneficially Owned(1)(2)	
	Number	%
<b>Directors and Executive Officers:</b>		
Jinsheng Ren(3)	39,616,590	38.6
Guoqiang Lin	*	*
Hongquan Liu	*	*
John Huan Zhao(4)	17,924,692	17.5
Yehong Zhang	*	*
Yushan Wan	*	*
Jindong Zhou	*	*
Xiaojin Yin	*	*
Jialun Tian	*	*
Quanfu Feng	*	*
Peng Wang	*	*
Haibo Qian	*	*
Jie Liu D Elia	*	*
All directors and executive officers as a group	57,541,282	56.1
<b>Principal Shareholders:</b>		
New Good Management Limited(5)	37,550,602	36.0
Assure Ahead Investments Limited(6)	17,924,692	17.5
King View Development International Limited(7)	11,820,000	11.5
Fosun Industrial Co., Limited(8)	8,039,074	7.8
Amy Liu(9)	6,631,032	6.5

\* Upon exercise of all options granted, would beneficially own less than 1.0% of our outstanding ordinary shares.

(1) Beneficial ownership is determined in accordance with Rule 13d-3 of the General Rules and Regulations under the Exchange Act, and includes voting or investment power with respect to the securities.

(2) The number of shares outstanding in calculating the percentages for each listed person includes, as applicable, (i) the ordinary shares underlying share options exercisable by such person, and (ii) restricted shares awarded to such person that are vested but yet to be duly registered or that can be vested, in each case within 60 days of the date of this annual report. Percentage of beneficial ownership of each listed person is based on 102,564,528 ordinary shares outstanding as of April 19, 2013 and, as applicable, (i) the ordinary shares underlying share options exercisable by such person and (ii) restricted shares awarded to such person that are vested but yet to be duly registered or that can be vested, in each case within 60 days of the date of this annual report.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

### Table of Contents

(3) Includes 36,950,602 ordinary shares directly held by New Good Management Limited, a British Virgin Islands company, which is controlled by Mr. Ren, and 2,665,988 restricted shares that have vested as of the date hereof. Mr. Ren is the chairman of the board of directors and the controlling shareholder of New Good Management Limited.

(4) Represents 17,924,692 ordinary shares directly held by Assure Ahead Investments Limited. Mr. Zhao, a director of Assure Ahead Investments Limited, disclaims beneficial ownership of shares held by Assure Ahead Investments Limited except to the extent of his pecuniary interests in those shares.

(5) New Good Management Limited is a British Virgin Islands company that is controlled by Mr. Jinsheng Ren and beneficially owned by Messrs. Jinsheng Ren, Jindong Zhou, Feifei Gao, Weidong Ren, Xiaojin Yin, Haibo Qian, Suqin Peng and Yong Ren. Mr. Ren is the chairman of the board of directors and the controlling shareholder of New Good Management Limited. The address of New Good Management Limited is at the offices of Offshore Incorporations Limited, P.O. Box 957, Offshore Incorporations Centre, Road Town, Tortola, and British Virgin Islands.

(6) Assure Ahead Investments Limited is a British Virgin Islands company that is 100.0% owned by Hony Capital II, L.P., an exempted limited partnership formed under the laws of the Cayman Islands; Hony Capital II, L.P.'s general partner is Hony Capital II GP Ltd., which is wholly owned by Legend Holdings Limited (through its wholly owned subsidiary, Right Lane Limited), an investment holding company incorporated in the PRC. Legend Holdings Limited is 36% owned by Chinese Academy of Sciences Holdings Co., Ltd, an asset management vehicle wholly owned by the Chinese Academy of Sciences, or CAS. CAS is a national academic and research institution owned and controlled by the PRC government. The address for Assure Ahead Investments Limited is at the offices of Offshore Incorporations Limited, P.O. Box 957, Offshore Incorporations Centre, Road Town, Tortola, British Virgin Islands. The directors of Assure Ahead Investments Limited, Shunlong Wang and So Wai Yin have voting and investment power over the shares that this shareholder beneficially owns.

(7) King View Development International Limited is a British Virgin Islands company and a wholly owned subsidiary of Trustbridge Partners II, L.P., a limited partnership whose general partner is TB Partners GP2, L.P. The general partner of TB Partners GP2, L.P. is TB Partners GP Limited. The address of King View Development International Limited is 2701B, Azia Center, 1233 Lujiazui Ring Road, Shanghai, People's Republic of China. The investment committee of Trustbridge Partners II, L.P. has voting and investment power over the shares that this shareholder beneficially owns.

In connection with New Good Management's private sale of 11,820,000 of our ordinary shares to King View Development International Limited in May 2008, New Good Management repurchased some of its own shares from some of its shareholders other than Mr. Ren and reduced the number of its total outstanding shares. Also in May 2008, Mr. Ren transferred some of his shares in New Good Management to Suqin Peng. As a result of the foregoing, Mr. Ren's percentage of beneficial ownership in New Good Management increased from approximately 49.1% to approximately 51.1% in May 2008 and Mr. Ren became the controlling shareholder of New Good Management. According to Rule 13d-3 of the General Rules and Regulations under the Exchange Act, Mr. Ren is deemed to have acquired indirect beneficial ownership of all of our ordinary shares that are directly held by New Good Management in May 2008.

(8) Beneficial ownership calculation is based solely on a review of a Schedule 13D/A filing made with the SEC on March 21, 2012.



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

(9) Beneficial ownership calculation is based solely on a review of a Schedule 13D/A filing made with the SEC on April 10, 2013.

To our knowledge, as of April 19, 2013, other than the 33.8% of our ordinary shares underlying our ADSs which were held by The Bank of New York Mellon, the depository of our ADR program, none of our ordinary shares were held in the United States. None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

For the options and restricted shares granted to our directors, officers and employees, see Item 6. Directors, Senior Management and Employees B. Compensation.

Table of Contents

**Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

*A. Major Shareholders*

Please refer to Item 6. Directors, Senior Management and Employees E. Share Ownership.

*B. Related Party Transactions*

**Transactions with Companies in which a Major Shareholder had Equity Interests**

We purchased packaging and raw materials from Simcere Zaikang Jiangsu Medical Co., Ltd, or Simcere Chain Drug Store, a subsidiary of Jiangsu Simcere China Drug Store Co., Ltd. in which certain shareholders of New Good Management Limited held equity interests, amounting to approximately nil, nil and RMB0.04 million (\$0.01 million) in 2010, 2011 and 2012, respectively.

We also sold pharmaceutical products to Simcere Chain Drug Store. In 2010, 2011 and 2012, we sold pharmaceutical products to this related party amounting to nil, nil and RMB0.3 million (\$0.05 million), respectively. We also sold pharmaceutical products to Jiangsu Simcere Zaikang Medical Co., Ltd, in which certain shareholders of New Good Management Limited held equity interests, amounting to RMB6.2 million, RMB8.7 million, RMB5.6 million (\$0.9 million) in 2010, 2011 and 2012, respectively. We purchased the packaging materials and sold the pharmaceutical products in the normal course of business at prices determined on an arm's length basis.

In 2012, we borrowed loans of RMB15 million (\$2.4 million) for daily operation from Hainan Simcere Xinji Investment Co., Ltd. in which a major shareholder of the Company has an equity interest, and repaid in 2012.

**Transactions with a Minority Shareholder**

In 2008, we provided an RMB20.0 million secured loan to the noncontrolling shareholder of Simcere Zhong Ren for its operating purpose. The loan bears a floating interest rate and is secured by the noncontrolling shareholder's entire equity interest in Simcere Zhong Ren. On July 1, 2009 and 2010, the loan together with the accumulated interest of RMB1.6 million was renewed and extended for another one year. On July 1, 2011, the loan was renewed and agreed to be repaid in installments, with RMB5.6 million, RMB10.0 million and RMB6.0 million to be repaid before June 30, 2012, 2013 and 2014, respectively. RMB5.6 million (\$0.9 million) of the principal amount and RMB2.7 million (\$0.4 million) of accrued interest were repaid in 2012.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

In 2012, we purchased raw materials from the noncontrolling shareholder of Simcere Zhong Ren, amounting to RMB0.5 million (\$0.1 million). We purchased the pharmaceutical products in the normal course of business at prices determined on an arm's length basis.

In 2012, we advanced to the noncontrolling shareholder of Simcere Zhong Ren for research and development services, amounting to RMB5.0 million (\$0.8 million).

### **Transactions with an Affiliated Companies**

In 2012, we sold pharmaceutical products to Simcere MSD, our affiliated company, amounting to RMB29.0 million (\$4.6 million). We sold the pharmaceutical products in the normal course of business at prices determined on an arm's length basis.

### **Share Incentives**

See Item 6. Directors, Senior Management and Employees B. Compensation 2006 Share Incentive Plan.

Table of Contents

**Registration Rights Agreements**

Set forth below is a description of the registration rights we granted to Assure Ahead Investments Limited, one of the selling shareholders, on November 20, 2006:

- *Demand Registration Rights.* At any time commencing the earlier of November 20, 2008 or six months after our initial public offering, shares held by Assure Ahead Investments Limited or its transferees and assignees have the right to demand that we file a registration statement under the Securities Act covering the offer and sale of their securities, so long as the aggregate amount of securities to be sold under the registration statement exceeds \$20.0 million. We are obligated under the registration rights agreement to use our best efforts to register our ordinary shares for resale if Assure Ahead Investments Limited makes such request. However, we are not required to provide for any payment or transfer any other consideration to Assure Ahead Investments Limited in the event of non-performance. We have the ability to delay or withdraw the filing of a registration statement for up to 90 days if we furnish to Assure Ahead Investments Limited or their transferees and assignees a certificate signed by our chief executive officer or our chairman of the board of directors stating that, board of directors determines it would be seriously detrimental to us or our shareholders for a registration statement to be filed in the near future. We are not obligated to affect such demand registrations on more than two occasions.
- *Form F-3 or S-3 Registration Rights.* Upon our company becoming eligible for use of Form F-3 or S-3, Assure Ahead Investments Limited or their transferees and assignees have the right to request that we file a registration statement under Form F-3 or S-3, so long as the aggregate amount of securities to be sold under the registration statement exceeds \$1.0 million. Such requests for registrations are not counted as demand registrations.
- *Piggyback Registration Rights.* If we propose to file a registration statement with respect to an offering for our own account or for the account of any person that is not Assure Ahead Investments Limited or their transferees and assignees, we must offer Assure Ahead Investments Limited or their transferees and assignees the opportunity to include their securities in the registration statement. We must use our reasonable best efforts to cause the underwriters in any underwritten offering to permit any such shareholder who so requests to include their securities on the same terms and conditions as the securities of our company.
- *Expenses of Registration.* We will pay all expenses relating to any demand or piggyback registration, whether or not such registrations become effective, except that shareholders shall bear the expense of any broker's commission or underwriter's discount or commission relating to registration and sale of their securities.

In July 2008, we filed a registration statement under Form F-3 (File No. 333-152101), as amended, for the sale of an aggregate of 10,166,454 ADSs representing 20,332,908 ordinary shares, consisting of 11,820,000 ordinary shares held by King View Development International Limited and 8,512,908 ordinary shares held by certain transferees of Assure Ahead Investments Limited.

In July 2009, we filed a registration statement under Form F-3 (File No. 333-160543), as amended, for the sale of an aggregate of 8,962,346 ADSs representing 17,924,692 ordinary shares held by Assure Ahead Investments Limited.

C. *Interests of Experts and Counsel*

Not applicable.

Table of Contents

**Item 8. FINANCIAL INFORMATION**

*A. Consolidated Statements and Other Financial Information*

See Item 18. Financial Statements.

**Legal and Administrative Proceedings**

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% equity interest in Jiangsu Quanyi for cash consideration. After we entered into the share purchase agreements in October and November 2009 to acquire 15% 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 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. See Item 3. Key Information D. Risk Factors Risks Related to Our Company 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.

In August 2011, Shandong Simcere filed lawsuits in 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. The lawsuits are still pending as of the Latest Practicable Date.

In addition, 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 selling shareholders of China Vax and certain former directors China Vax appointed, 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 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 two of its former directors and their affiliates to seek damages for RMB178.0 million. 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.



Table of Contents

In December 2011, certain batches of azithromycin granules produced by Nanjing Simcere Dongyuan were found to have failed to comply with applicable pharmaceutical standards. As a result, our incomes 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.

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. See Item 3. Key Information D. Risk Factors Risks Related to Our Company 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 are currently not a party to any other material legal or administrative proceedings, and we are not aware of any other threatened material legal or administrative proceedings against us. We may from time to time become a party to various legal or administrative proceedings arising in the ordinary course of our business.

**Dividend Policy**

Our board of directors has complete discretion on whether to pay dividends. Even if our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board of directors may deem relevant.

Since our incorporation, we have never declared or paid any dividends, nor do we currently have any present plan to pay any cash dividends on our ordinary shares in the foreseeable future. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business.

If we pay any dividends, we will pay our ADS holders to the same extent as holders of our ordinary shares, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

*B. Significant Changes*

We have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

**Item 9. THE OFFER AND LISTING**



Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

A. *Offering and Listing Details*

Our ADSs, each representing two of our ordinary shares, have been listed on the New York Stock Exchange since April 20, 2007 under the symbol SCR. For the period from April 20, 2007 to April 19, 2013, the trading price of our ADSs on New York Stock Exchange ranged from \$19.30 to \$4.41 per ADS.

The following table provides the high and low trading prices for our ADSs on the New York Stock Exchange for the period indicated.

	Sales Price	
	High	Low
<b>2007</b> (from April 20, 2007)	\$ 19.30	\$ 10.81
<b>2008</b>	\$ 15.88	\$ 4.41
<b>2009</b>	\$ 10.03	\$ 4.76
<b>2010</b>	\$ 12.98	\$ 7.44
<b>2011</b>	\$ 13.75	\$ 7.12
<b>2012</b>		
<b>Quarterly Highs and Lows</b>		
First Quarter 2011	\$ 13.75	\$ 11.32
Second Quarter 2011	\$ 13.48	\$ 8.65
Third Quarter 2011	\$ 12.14	\$ 7.93
Fourth Quarter 2011	\$ 9.70	\$ 7.12
First Quarter 2012	\$ 10.36	\$ 7.96
Second Quarter 2012	\$ 9.45	\$ 8.01
Third Quarter 2012	\$ 9.09	\$ 7.30
Fourth Quarter 2012	\$ 8.90	\$ 7.50
<b>Monthly Highs and Lows</b>		
October 2012	\$ 8.90	\$ 7.85
November 2012	\$ 8.27	\$ 7.50
December 2012	\$ 8.38	\$ 7.50
January 2013	\$ 8.16	\$ 7.25
February 2013	\$ 8.05	\$ 7.34
March 2013	\$ 9.59	\$ 7.80
April 2013 (through April 19, 2013)	\$ 9.29	\$ 8.84

Table of Contents

*B. Plan of Distribution*

Not applicable.

*C. Markets*

Our ADSs, each representing two of our ordinary shares, have been listed on the New York Stock Exchange since April 20, 2007 under the symbol SCR.

*D. Selling Shareholders*

Not applicable.

*E. Dilution*

Not applicable.

*F. Expenses of the Issue*

Not applicable.

**Item 10. ADDITIONAL INFORMATION**

*A. Share Capital*

Not applicable.

*B. Memorandum and Articles of Association*

We incorporate by reference into this annual report the description of our second amended and restated memorandum of association contained in our F-1 registration statement (File No. 333-141539), as amended, filed with the Commission on March 23, 2007. Our shareholders adopted our amended and restated memorandum and articles of association by unanimous resolutions on March 23, 2007.

Table of Contents

*C. Material Contracts*

We have not entered into any material contracts other than in the ordinary course of business and other than those described in Item 4. Information on the Company or elsewhere in this annual report on Form 20-F.

*D. Exchange Controls*

**Foreign Currency Exchange**

Foreign currency exchange regulation in China is primarily governed by the following rules:

Foreign Currency Administration Rules (2008), as amended, or the Exchange Rules; Under the Exchange Rules, the Renminbi is convertible for current account items, including interest payments and trade and service-related foreign exchange transactions. Conversion of Renminbi for capital account items, such as direct investment, loan, security investment and repatriation of investment, however, is still subject to the approval of the SAFE.

Under the Administration Rules, foreign-invested enterprises in China, may only buy, sell and/or remit foreign currencies at those banks authorized to conduct foreign exchange business after providing valid commercial documents and, in the case of capital account item transactions, obtaining approval from the SAFE. Capital investments by foreign-invested enterprises outside of China are also subject to limitations, which include approvals by the SAFE and other relevant government authorities.

*E. Taxation*

**Cayman Islands Taxation**

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. No Cayman Islands stamp duty will be payable unless an instrument is executed in, brought to, or produced before a court of the Cayman Islands. The Cayman Islands are not parties to any double tax treaties. There are no exchange control regulations or currency restrictions in the Cayman Islands.

**People's Republic of China Taxation**

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

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

Table of Contents

**United States Federal Income Taxation**

The following discussion describes certain United States federal income tax consequences to U.S. Holders (defined below) under present law of an investment in the ADSs or ordinary shares subsequently received in exchange for ADSs. This summary applies only to U.S. Holders that hold the ADSs or ordinary shares as capital assets and that have the U.S. dollar as their functional currency. This discussion is based on the Internal Revenue Code of 1986, as amended (the Code) as in effect on the date of this annual report on Form 20-F and on United States Treasury regulations in effect or, in some cases, proposed, as of the date of this annual report on Form 20-F, as well as judicial decisions and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below.

As used herein, the term U.S. Holder means a holder of an ADS or ordinary share that is for United States federal income tax purposes:

- an individual citizen or resident of the United States;
  
- a corporation (or other entity treated as a corporation for United States federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
  
- an estate the income of which is subject to United States federal income taxation regardless of its source; or
  
- a trust that (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons control all substantial decisions of the trust or (2) has a valid election in effect under applicable United States Treasury regulations to be treated as a U.S. person.

The following discussion does not represent a detailed description of the United States federal income tax consequences applicable to persons subject to special treatment under United States federal income tax laws such as:

- a dealer in securities or currencies;
  
- certain financial institutions;

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- broker dealers;
- U.S. expatriates;
- traders that elect to mark to market;
- tax-exempt entities;
- persons liable for alternative minimum tax;
- persons holding an ADS or ordinary share as part of a straddle, constructive sale, hedging, conversion or integrated transaction;
- persons whose functional currency is not the U.S. dollar; or
- persons that actually or constructively own 10.0% or more of our voting stock.

Table of Contents

If you are a partner in partnership or other entity taxable as a partnership that holds ADSs or ordinary shares, your tax treatment generally will depend on your status and the activities of the partnership. If you are a partner of a partnership holding the ADSs or ordinary shares, you should consult your own tax advisors.

The discussion below does not contain a detailed description of all the United States federal income tax consequences to you in light of your particular circumstances nor does it address any United States federal tax laws other than United States federal income tax laws. If you are considering the purchase of the ADSs or ordinary shares, you should consult your own tax advisors concerning the particular United States federal income tax consequences to you of your acquisition, ownership and disposition of the ADSs or ordinary shares, as well as the consequences to you arising under the laws of any other taxing jurisdiction.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. If you hold ADSs, you should be treated as the holder of the underlying ordinary shares represented by those ADSs for U.S. federal income tax purposes. Exchanges of ordinary shares for ADSs and ADSs for ordinary shares generally will not be subject to United States federal income tax.

***Taxation of Dividends and Other Distributions on the ADSs or Ordinary Shares***

Subject to the passive foreign investment company rules discussed below, the gross amount of all our distributions to you with respect to the ADSs or ordinary shares will be included in your gross income as dividend income on the date of actual or constructive receipt by the depository, in the case of ADSs, or by you, in the case of ordinary shares, but only to the extent that the distribution is paid out of our current or accumulated earnings and profits, as determined under United States federal income tax principles. The dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other United States corporations.

With respect to non-corporate U.S. Holders including individual U.S. Holders, for taxable years beginning before January 1, 2013, dividends may be taxed at the lower applicable capital gains rate, and thus may constitute qualified dividend income, provided that (1) either (a) the ADSs or ordinary shares are readily tradable on an established securities market in the United States or (b) we are eligible for the benefits of a qualifying income tax treaty with the United States that includes an exchange of information program (2) we are not a passive foreign investment company (as discussed below) for either our taxable year in which the dividend was paid or the preceding taxable year, and (3) certain holding period requirements are met. The New York Stock Exchange, on which the ADSs are traded, should be considered to be an established securities market in the United States for this purpose. If we are deemed to be a resident enterprise under PRC tax law, you may be eligible for the benefits of the income tax treaty between the United States and the PRC. You should consult your tax advisors regarding the availability of the lower rate for dividends paid with respect to our ADSs or ordinary shares.



Table of Contents

In the event that we are deemed to be a PRC resident enterprise under PRC tax law, you may be subject to PRC withholding taxes on dividends payable to you with respect to the ADSs or ordinary shares. In that case, subject to certain conditions and limitations, PRC withholding taxes on dividends, if any, may be treated as foreign taxes eligible for credit against your U.S. federal income tax liability. For purposes of calculating the foreign tax credit, dividends paid to you with respect to the ADSs or ordinary shares will be treated as income from sources outside the United States and will generally constitute passive category income but could, in the case of certain U.S. Holders, constitute general category income. The rules governing the foreign tax credit are complex. You are urged to consult your tax advisors regarding the availability of the foreign tax credit under your particular circumstances.

To the extent that the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a tax-free return of your tax basis in your ADSs or ordinary shares, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect that a distribution will generally be treated as a dividend.

***Taxation of Disposition of ADSs or Ordinary Shares***

Subject to the passive foreign investment company rules discussed below, you will recognize taxable gain or loss on any sale, exchange or other taxable disposition of an ADS or ordinary share equal to the difference between the amount realized for the ADS or ordinary share and your tax basis in the ADS or ordinary share. The gain or loss generally will be capital gain or loss. If you are a non-corporate U.S. Holder, including an individual U.S. Holder, who has held the ADS or ordinary share for more than one year, you will be eligible for reduced tax rates. The deductibility of capital losses is subject to limitations. Any such gain or loss that you recognize will generally be treated as United States source income or loss for foreign tax credit limitation purposes. However, in the event that we are deemed to be a PRC resident enterprise under PRC tax law, we may be eligible for the benefits of the income tax treaty between the United States and the PRC. Under that treaty, if any PRC tax were to be imposed on any gain from the disposition of the ADSs or ordinary shares, the gain may be treated as PRC-source income. You are urged to consult your tax advisors regarding the tax consequences if a foreign withholding tax is imposed on a disposition of ADSs or ordinary shares, including the availability of the foreign tax credit under your particular circumstances.

***Passive Foreign Investment Company***

We believe that we were not a passive foreign investment company, or PFIC, for United States federal income tax purposes for our taxable year ended December 31, 2012, and we do not expect to become one for our current taxable year or in the future, although there can be no assurance in this regard.

A non-U.S. corporation is considered to be a PFIC for any taxable year if either:

- at least 75% of its gross income is passive income; or

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

Passive income generally includes dividends, interest, royalties, rents (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gain from assets that produce passive income. We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation in which we own, directly or indirectly, more than 25% (by value) of the stock.

Table of Contents

We must make a separate determination each year as to whether we are a PFIC. Accordingly, it is possible that we may become a PFIC in the current or any future taxable year due to changes in our income or asset composition. As a result, our PFIC status may change. In particular, because we have valued our goodwill based on the market value of our ADSs, our PFIC status may be determined in large part based on the market price of our ADSs, which is likely to fluctuate, and which may result in our being a PFIC for any year. If we are a PFIC for any year during which you hold ADSs or ordinary shares, we generally will continue to be treated as a PFIC for all succeeding years during which you hold ADSs or ordinary shares.

If we are a PFIC for any taxable year during which you hold ADSs or ordinary shares, you will be subject to special tax rules with respect to any excess distribution that you receive and any gain you realize from a sale or other disposition (including a pledge) of the ADSs or ordinary shares, unless you make a mark-to-market election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ADSs or ordinary shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs or ordinary shares;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or excess distribution cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ADSs or ordinary shares cannot be treated as capital, even if you hold the ADSs or ordinary shares as capital assets.

Alternatively, a U.S. Holder of marketable stock (as defined below) in a PFIC may make a mark-to-market election for such stock of a PFIC to elect out of the tax treatment discussed in the two preceding paragraphs. If you make a timely mark-to-market election for the ADSs or ordinary shares, you will include in income each year an amount equal to the excess, if any, of the fair market value of the ADSs or ordinary shares as of the close of your taxable year over your adjusted basis in such ADSs or ordinary shares. You are allowed a deduction for the excess, if any, of the adjusted basis of the ADSs or ordinary shares over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs or ordinary shares included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ADSs or ordinary shares, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ADSs or ordinary shares, as well as to any loss realized on the actual sale or disposition of the ADSs or ordinary shares, to the extent that the amount of such loss does not exceed the net mark-to-market gains previously included for such ADSs or ordinary shares. Your basis in the ADSs or ordinary shares will be adjusted to reflect any such income or loss amounts.

The mark-to-market election is available only for marketable stock, which is stock that is regularly traded in other than de minimis quantities on at least 15 days during each calendar quarter on a qualified exchange, including the New York Stock Exchange, or other market, as defined in

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

applicable U.S. Treasury regulations. There can be no assurance that the ADSs will be treated as regularly traded on the New York Stock Exchange.

Table of Contents

Alternatively, a United States shareholder of a PFIC may avoid the rules described above by electing to treat a PFIC as a qualified electing fund under Section 1295 of the Code. This option is not available to you because we do not intend to comply with the requirements necessary to permit you to make this election.

If you hold ADSs or ordinary shares in any year in which we are a PFIC, you will be required to file Internal Revenue Service Form 8621 regarding distributions received on the ADSs or ordinary shares and any gain realized on the disposition of the ADSs or ordinary shares (or to file such other information as may be required by the United States Treasury Department).

You are urged to consult your tax advisor regarding the application of the PFIC rules to your investment in ADSs or ordinary shares.

***Information Reporting and Backup Withholding***

Dividend payments with respect to ADSs or ordinary shares and proceeds from the sale, exchange or redemption of ADSs or ordinary shares may be subject to information reporting to the Internal Revenue Service. Backup withholding will not apply to a U.S. Holder who furnishes a correct taxpayer identification number and makes any other required certification or who is otherwise exempt from backup withholding. U.S. Holders who are required to establish their exempt status generally must provide such certification on Internal Revenue Service Form W-9. You are urged to consult your tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. federal income tax liability, if any, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information in a timely manner.

Certain U.S. Holders who are individuals that hold certain foreign financial assets (which may include ADSs or ordinary shares) may be required to report information relating to such assets. You should consult your tax advisor regarding the effect, if any, of this reporting requirement on your ownership and disposition of ADSs or ordinary shares.

*F. Dividends and Paying Agents*

Not applicable.

*G. Statement by Experts*

Not applicable.

*H. Documents on Display*

We have filed this annual report on Form 20-F, including exhibits, with the SEC. As allowed by the SEC, in Item 19 of this annual report, we incorporate by reference certain information we filed with the SEC. This means that we can disclose important information to you by referring you to another document filed separately with the SEC.

You may read and copy this annual report, including the exhibits incorporated by reference in this annual report, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 and at the SEC's regional offices in New York, New York and Chicago, Illinois. You can also request copies of this annual report, including the exhibits incorporated by reference in this annual report, upon payment of a duplicating fee, by writing information on the operation of the SEC's Public Reference Room.

Table of Contents

The SEC also maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy statements and other information regarding registrants that file electronically with the SEC. Our annual report and some of the other information submitted by us to the SEC may be accessed through this web site.

As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

Our financial statements have been prepared in accordance with U.S. GAAP.

We will furnish our shareholders with annual reports, which will include a review of operations and annual audited consolidated financial statements prepared in conformity with U.S. GAAP.

*I. Subsidiary Information*

For a listing of our subsidiaries, see Item 4. Information on the Company C. Organizational Structure in this annual report.

**Item 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

*Foreign Currency Exchange Risk*

Our revenues, costs and expenses are currently denominated primarily in Renminbi. As a result, fluctuations in the value of Renminbi against other currencies may affect the price competitiveness of our products versus competitor products from multinational pharmaceutical companies. Although the conversion of the Renminbi is highly regulated in China, the value of the Renminbi against the value of the U.S. dollar or any other currency nonetheless may fluctuate and be affected by, among other things, changes in China's political and economic conditions. Under the currency policy in effect in China today, the Renminbi is permitted to fluctuate in value within a narrow band against a basket of certain foreign currencies. China is currently under significant international pressures to liberalize this government currency policy, and if such liberalization were to occur, the value of the Renminbi could appreciate or depreciate against the U.S. dollar.

We use Renminbi as the reporting currency for our financial statements. The functional currency of our subsidiaries in China is Renminbi.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Transactions in foreign currencies are translated into the functional currency at the exchange rate at the date of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the applicable exchange rate at the balance sheet date. The resulting exchange differences are recognized in our consolidated statements of comprehensive income. Our company has used a substantial portion of the proceeds from our initial public offering to provide U.S. dollar-denominated intercompany loans to our PRC subsidiaries where such funds were converted into Renminbi. As these intercompany loans are not considered long-term investment in nature and given that the functional currency of our company is U.S. dollars and the functional currency of our PRC subsidiaries is Renminbi, gain arising from the translation of the intercompany loans from U.S. dollars to Renminbi by our PRC subsidiaries is recognized in our consolidated statements of comprehensive income while gain or loss arising from the translation of our company's U.S. dollars financial statements to Renminbi for consolidation purpose is recognized in our consolidated statement of shareholders' equity and comprehensive income. We recognized foreign currency exchange gains of RMB5.5 million and RMB7.7 million in 2010 and 2011, respectively. In 2012, we recognized foreign currency exchange losses of RMB0.9 million (\$0.1 million), which mainly represent realized losses recognized by our PRC subsidiaries from the translation of U.S. dollar-denominated intercompany loans.



Table of Contents

Assets and liabilities of our subsidiaries whose functional currency is not Renminbi, are translated into Renminbi at the exchange rates at the balance sheet date. Income and expense items are translated at the average rates of exchange prevailing during the period. The adjustment resulting from translating the financial statements of such entities is reflected as a component of accumulated other comprehensive loss within shareholders' equity.

Fluctuations in exchange rates may affect our financial performance. Appreciation of Renminbi against the U.S. dollar would have an adverse effect on Renminbi amount that we receive from the conversion. Conversely, if we decide to convert Renminbi into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against Renminbi would have a negative effect on the U.S. dollar amount available to us. As of December 31, 2012, a 1.0% change in the exchange rates between the Renminbi and the U.S. dollar would result in a translation gain or loss of RMB0.2 million (\$0.04 million).

The fluctuation in foreign exchange may impose certain exchange rate risks on us. Our exposure to foreign exchange risk primarily relates to cash denominated in U.S. dollars as a result of our past issuances of preferred shares through a private placement and proceeds from the initial public offering in April 2007. We have not hedged exposures in foreign currencies or enter into any other derivative financial instruments. Although in general, our exposure to foreign exchange risks should be limited, the value of your investment in our ADSs will be affected by the foreign exchange rate between U.S. dollars and RMB because the value of our business is effectively denominated in RMB, while the ADSs will be traded in U.S. dollars.

***Interest Rate Risk***

Our risk exposure from changes in interest rates relates primarily to the interest expenses associated with our short-term bank loans and borrowings, long term borrowings as well as the interest income generated by excess cash invested in demand and savings deposits. We currently do not, have not historically used, and do not expect to use in the future, any derivative financial instruments to manage our interest risk exposure. Interest-bearing investments and interest-bearing borrowings carry a degree of interest rate risk. If there were a 25 basis point increase or decrease in interest rates, the expected adverse impact on net income related to our financial instruments would be insignificant.

***Credit Risk with Financial Institutions***

We are exposed to counterparty risks related to certain financial assets including cash and investment securities. As of December 31, 2011 and 2012, RMB193.8 million and RMB164.8 million (\$26.5 million), respectively, in cash was held in uninsured accounts at major financial institutions located in the PRC.

**Item 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

**A. Debt Securities**

Not applicable.

*B. Warrants and Rights*

Not applicable.

*C. Other Securities*

Not applicable.

Table of Contents

D. *American Depositary Shares*

According to our Deposit Agreement with our ADS depository, The Bank of New York Mellon, the depository collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depository collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depository may collect its annual fee for depository services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depository may generally refuse to provide fee-attracting services until its fees for those services are paid.

<b>Persons depositing or withdrawing shares must pay:</b>	<b>For:</b>
\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	<ul style="list-style-type: none"> <li>• Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property; or</li> <li>• Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates</li> </ul>
\$.02 (or less) per ADS	<ul style="list-style-type: none"> <li>• Any cash distribution to you</li> </ul>
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	<ul style="list-style-type: none"> <li>• Distribution of securities distributed to holders of deposited securities that are distributed by the depository to ADS holders</li> </ul>
\$.02 (or less) per ADSs per calendar year	<ul style="list-style-type: none"> <li>• Depository services</li> </ul>
Registration or transfer fees	<ul style="list-style-type: none"> <li>• Transfer and registration of shares on our share register to or from the name of the depository or its agent when you deposit or withdraw shares</li> </ul>
<b>Persons depositing or withdrawing shares must pay:</b>	<b>For:</b>
Expenses of the depository	<ul style="list-style-type: none"> <li>• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement); or</li> <li>• Converting foreign currency to U.S. dollars</li> </ul>
Taxes and other governmental charges the depository or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes	<ul style="list-style-type: none"> <li>• As necessary</li> </ul>
Any charges incurred by the depository or its agents for servicing the deposited securities	<ul style="list-style-type: none"> <li>• As necessary</li> </ul>

The fees described above may be amended from time to time.

The depository has agreed to reimburse us for expenses we incur that are related to establishment and maintenance of the ADR program, including investor relations expenses and stock exchange application and listing fees. There are limits on the amount of expenses for which the

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

depository will reimburse us, but the amount of reimbursement available to us is not related to the amounts of fees the depository collects from investors. In 2012, we received an incentive payment of \$1.0 million (RMB0.2 million) from the depository relating to the ADS facility.

Table of Contents

**PART II**

**Item 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

None of these events occurred in any of the years ended December 31, 2010, 2011 and 2012.

**Item 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS**

See Item 10. Additional Information for a description of the rights of securities holders, which remain unchanged.

We completed our initial public offering of 31,250,000 ordinary shares, in the form of ADSs, at \$14.50 per ADS on April 20, 2007, after our ordinary shares and American Depositary Receipts were registered under the Securities Act. The effective date of our registration statement on Form F-1 (File number: 333-141539) was April 20, 2007. Goldman Sachs (Asia) L.L.C. acted as the sole global coordinator and the sole bookrunner for the offering.

In 2012, we have used the net proceeds received from our initial public offering as follows:

- Approximately RMB245.6 million (\$39.4 million) to fund our research and development efforts; and
- Approximately RMB121.9 million (\$19.3 million) for repurchase of our ordinary shares.

**Item 15. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

As of the end of the period covered by this annual report, an evaluation has been carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act. Based on

that evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act, for our company. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external reporting purposes in accordance with generally accepted accounting principles and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of a company's assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of a company's management and directors, and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of a company's assets that could have a material effect on the consolidated financial statements.

Table of Contents

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance with respect to consolidated financial statements preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As required by Section 404 of the Sarbanes-Oxley Act of 2002 and related rules as promulgated by the SEC, management assessed the effectiveness of the internal control over financial reporting as of December 31, 2012 using criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, management concluded that the our internal control over financial reporting was effective as of December 31, 2012 based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

**Attestation Report of the Registered Public Accounting Firm**

The effectiveness of internal control over financial reporting as of December 31, 2012 has been audited by KPMG, an independent registered public accounting firm, who has also audited our consolidated financial statements for the year ended December 31, 2012.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the period covered by this annual report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Report of Independent Registered Public Accounting Firm**

**The Board of Directors  
Simcere Pharmaceutical Group:**

We have audited Simcere Pharmaceutical Group's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Simcere Pharmaceutical Group's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Simcere Pharmaceutical Group's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.



Table of Contents

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Simcere Pharmaceutical Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Simcere Pharmaceutical Group and subsidiaries as of December 31, 2011 and 2012, and the related consolidated statements of comprehensive income, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2012, and our report dated April 25, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG

Hong Kong, China

April 25, 2013

Table of Contents

**Item 16. [RESERVED]**

**Item 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our board of directors has determined that Alan Au qualify as audit committee financial expert as defined in Item 16A of Form 20-F. Each of the members of the Audit Committee is an independent director as defined in the listing rules of New York Stock Exchange.

**Item 16B. CODE OF ETHICS**

Our board of directors has adopted a code of ethics that applies to our directors, officers, employees and agents, including certain provisions that specifically apply to our chief executive officer, chief financial officer, vice presidents and any other persons who perform similar functions for us. We have filed our code of business conduct and ethics as an exhibit to this annual report on Form 20-F. We hereby undertake to provide to any person without charge, a copy of our code of business conduct and ethics within ten working days after we receive such person's written request.

**Item 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by KPMG, our principal independent auditors, for the periods indicated. We did not pay any other fees to our auditors during the periods indicated below.

	Year Ended December 31,		
	2010	2011	2012
Audit fees(1)	\$ 1,586	\$ 1,663	\$ 1,737
Audit-related fees(2)	126	132	134
Tax fees(3)			7
Other fees			
<b>Total</b>	<b>\$ 1,712</b>	<b>\$ 1,795</b>	<b>\$ 1,878</b>

(1) Audit fees represent the aggregate fees billed for each of the fiscal years listed for professional services rendered by our principal auditors for the audit of our annual financial statements or services that are normally provided by the auditors in connection with statutory and regulatory filings or engagements.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

(2) Audit-related fees represent the aggregate fees billed in each of the fiscal years listed for assurance and related services by our principal auditors for services rendered that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under Audit fees. Services comprising the fees disclosed under the category of Audit-related fees in 2012 involve principally limited procedures performed on our condensed consolidated financial statements for the quarterly and year-to-date periods, which are included in our quarterly press release to be furnished in Form 6-K.

(3) Tax fees represent the fee billed for the transfer pricing advisory services.

The policy of our audit committee is to pre-approve all audit and non-audit services provided by KPMG, including audit services, audit-related services, tax services and other services as described above, other than those for de minimis services which are approved by the Audit Committee prior to the completion of the audit.

Table of Contents

**Item 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**Item 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

In November 2008, our board of directors approved a share repurchase program that authorizes us to purchase up to \$50.0 million of our issued and outstanding ADSs. In November 2009, our board of directors approved a new share repurchase program that authorizes us to purchase up to \$50.0 million of our issued and outstanding ADSs.

In 2008, we repurchased 3.0 million ordinary shares in the form of ADSs for an aggregate cost of \$10.0 million, which included \$0.1 million of handling charges. In 2009, we repurchased an aggregate of 12.2 million ordinary shares in the form of ADSs for an aggregate cost of \$43.6 million, which included \$0.5 million of handling charges. In 2010, we further repurchased an additional 4.3 million ordinary shares in the form of ADSs for an aggregate cost of 18.8 million, which included \$0.2 million of handling charge. All of the repurchased ordinary shares have been retired. The repurchases were made on the open market at prevailing market prices or in block trades and subject to restrictions relating to volume, price and timing. Any future repurchases, if any, will depend on prevailing market conditions, our liquidity requirements and other factors.

In November 2011, our board of directors approved a share repurchase program, under which we may purchase up to \$30 million of our issued and outstanding ADSs. The repurchases will be made from time to time on the open market at prevailing market prices or in block trades and subject to restrictions relating to volume, price and timing.

In 2011, we repurchased 1.3 million ordinary shares in the form of ADSs for an aggregate cost of \$5.0 million, which included \$0.05 million of handling charges. All of the repurchased ordinary shares have been cancelled in 2012.

In 2012, the Company repurchased 2.3 million ordinary shares in the form of ADSs for an aggregate cost of \$19.3 million (RMB121.9 million), which included \$0.2 million of handling charges. 2.0 million ADSs was cancelled in 2012 and the remaining 0.3 million ADSs was cancelled in 2013.

The following table sets forth certain information related to purchases made by us of our ADSs under the program:

<b>Period</b>	<b>Total number of ADSs purchased</b>	<b>Average price paid per ADS(1)</b>	<b>Total number of ADSs purchased as</b>	<b>Approximate dollar value of ADSs that may yet be purchased under the program</b>
---------------	---------------------------------------	--------------------------------------	--	---

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

		\$	RMB(2)	part of publicity announced program	\$	RMB(2)
November 10, 2008 to September 29, 2009	7,216,920	7.00	43.62	7,216,920		
November 18, 2009 to November 12, 2010	2,483,470	8.79	54.76	2,483,470		
November 17, 2011 to November 16, 2012	2,918,579	8.26	51.46	2,918,579		

---

(1) The average price paid per ADS is calculated using the execution price for each repurchase excluding commissions paid to brokers.

(2) The translations of U.S. dollar amounts into Renminbi amounts have been made at the noon buying rate in effect on December 31, 2012, which was \$1.00 to RMB6.2301. See Introduction and Part I. Item 3. Key Information Selected Financial Data Exchange Rate Information.

Table of Contents

**Item 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT**

Not applicable.

**Item 16G. CORPORATE GOVERNANCE**

We are a foreign private issuer (as such term is defined in Rule 3b-4 under the Exchange Act), and our ADSs, each representing two ordinary shares, are listed on the New York Stock Exchange. Under Section 303A of the New York Stock Exchange Listed Company Manual, New York Stock Exchange listed companies that are foreign private issuers are permitted to follow home country practice in lieu of the corporate governance provisions specified by the New York Stock Exchange with limited exceptions. The following summarizes some significant ways in which our corporate governance practices differ from those followed by domestic companies under the listing standards of the New York Stock Exchange.

- The New York Stock Exchange standards for domestic companies require that non-management directors meet at regularly scheduled executive sessions without management. Our non-management directors have not met in executive sessions without management, and there is no requirement under the laws of the Cayman Islands that our non-management directors meet in executive sessions.
- The NYSE standards for domestic companies require that the audit committee must have a minimum of three members. As a foreign private issuer, we are not required to comply with such requirement. As of the date of this annual report, our audit committee consists of two members, each of whom satisfies the independence requirements of Section 303A of the NYSE Listed Company Manual and Rule 10A-3 under the Exchange Act, and one such member qualifies as an audit committee financial expert under applicable SEC rules.
- The NYSE standards for domestic companies require that the compensation committee composed entirely of independent directors. As a foreign private issuer, we are not required to comply with such requirement. As of the date of this annual report, our compensation committee consists of two members, one of whom satisfies the independence requirements of Section 303A of the NYSE Listed Company Manual.
- The NYSE standards for domestic companies require that listed companies must have a majority of independent directors. As a foreign private issuer, we are not required to comply with such requirement. As of the date of this annual report, our board of directors consists of five members, two of whom satisfy the independence requirements of Section 303A of the NYSE Listed Company Manual.

**Item 16H. MINE SAFETY DISCLOSURE**

Not applicable.

Table of Contents

**PART III**

**Item 17. FINANCIAL STATEMENTS**

We have elected to provide financial statements pursuant to Item 18.

**Item 18. FINANCIAL STATEMENTS**

Our consolidated financial statements are included at the end of this annual report.

**Item 19. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Document</b>
1.1	Second Amended and Restated Memorandum and Articles of Association of the Registrant
2.1	Registrant's Form of American Depositary Receipt
2.2	Registrant's Specimen Certificate for Ordinary Shares
2.3	Form of Deposit Agreement among the Registrant, the depositary and Owners and Beneficial Owners of the American Depositary Shares issued thereunder
2.4	Registration Rights Agreement among Simcere Pharmaceutical Group, New Good Management Limited and Assure Ahead Investments Limited, dated November 20, 2006
2.5	Share Purchase Agreement among Luo Yongzhang, Zhou Bing and State Good Group Limited, dated May 28, 2006
2.6	Share Purchase Agreement among Yantai Rongchang Pharmaceutical Co., Ltd., Beijing Scientific Town Development Co., Ltd., Yantai Ruikang Biochemical Drugs LLC and Simcere Pharmaceutical Company Limited, dated May 28, 2006
2.7	Registration Rights Agreement among Simcere Pharmaceutical Group, New Good Management Limited and King View Development International Limited, dated May 12, 2008
4.1	Form of Indemnification Agreement with the Registrant's directors
4.2	Form of Employment Agreement of senior executive officers
4.3	Form of Non-Disclosure, Non-Competition and Proprietary Information Agreement
4.4	2006 Share Incentive Plan adopted as of November 13, 2006
4.5	Cooperation Agreement on the Incorporation of Medgenn (Hong Kong) Ltd. entered into between Bestspeed Investments Limited (BVI) and Yantai Medgenn Co., Ltd., dated February 10, 2005
4.6	Implementation Rules of Supplementary Agreement on Cooperation Agreement on the Incorporation of Medgenn (Hong Kong) Ltd. entered into between Yantai Medgenn Co., Ltd. and Medgenn (Hong Kong) Co., Ltd., dated August 6, 2005
4.7	Joint Research Agreement on Anti-Tumor Drug AL6802 entered into between Jiangsu Simcere Pharmaceutical R&D Co., Ltd. and Advenchen Laboratories LLC, dated January 8, 2007
4.8*	2008 Stock Incentive Plan adopted as of July 31, 2008.
8.1*	Subsidiaries of the Registrant
11.1	Code of Business Conduct and Ethics
12.1*	CEO Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002



## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

12.2*	CFO Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1*	CEO Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2*	CFO Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of KPMG
101.INS	XBRL Instance Document. **
101.SCH	XBRL Taxonomy Extension Schema Document. **
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document. **
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document. **
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document. **
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document. **

---

\* Filed herewith.

\*\* XBRL (eXtensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

Table of Contents

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Simcere Pharmaceutical Group

By:

/s/ Hongquan Liu  
Name: Hongquan Liu  
Title: Chief Executive Officer

Date: April 26, 2013

Table of Contents

**SIMCERE PHARMACEUTICAL GROUP AND SUBSIDIARIES  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<b>Contents</b>	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2011 and 2012</u>	F-3
<u>Consolidated Statements of Comprehensive Income for the years ended December 31, 2010, 2011 and 2012</u>	F-4
<u>Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2010, 2011 and 2012</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2011 and 2012</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-9

Table of Contents

**Report of Independent Registered Public Accounting Firm**

**The Board of Directors  
Simcere Pharmaceutical Group:**

We have audited the accompanying consolidated balance sheets of Simcere Pharmaceutical Group and subsidiaries as of December 31, 2011 and 2012, and the related consolidated statements of comprehensive income, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2012. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Simcere Pharmaceutical Group and subsidiaries as of December 31, 2011 and 2012, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements as of and for the year ended December 31, 2012 have been translated into United States dollars solely for the convenience of the reader. We have audited the translation and, in our opinion, the consolidated financial statements expressed in Renminbi have been translated into United States dollars on the basis set forth in Note 2(c) to the consolidated financial statements.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Simcere Pharmaceutical Group's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated April 25, 2013 expressed an unqualified opinion on the effectiveness of the Simcere Pharmaceutical Group's internal control over financial reporting.

/s/ KPMG

Hong Kong, China  
April 25, 2013



Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Consolidated Balance Sheets**

(Amounts expressed in thousands, except share data)

	Note	2011 RMB	December 31, 2012 2012 RMB	2012 US\$
<b>Assets</b>				
<b>Current assets</b>				
Cash		209,850	178,162	28,597
Pledged bank deposits		52,707	23,394	3,755
Assets held for sale	1(c)		90,550	14,534
Accounts and bills receivable, net	3	1,276,872	1,093,111	175,456
Inventories	4	126,708	120,932	19,411
Deferred tax assets	10(d)	79,620	111,706	17,930
Other current assets	19	101,576	125,542	20,151
<b>Total current assets</b>		<b>1,847,333</b>	<b>1,743,397</b>	<b>279,834</b>
Property, plant and equipment, net	5	925,815	853,546	137,004
Land use rights	6	139,707	128,220	20,581
Intangible assets, net	7(d)	338,472	234,714	37,674
Goodwill	7(e)	309,936	284,620	45,685
Investments in and advances to affiliated companies	1(c) and 7(a)	91,355	56,785	9,115
Other non-current assets	19	81,499	71,381	11,457
<b>Total assets</b>		<b>3,734,117</b>	<b>3,372,663</b>	<b>541,350</b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Short-term borrowings	8	816,150	675,779	108,470
Accounts and bills payable		80,570	62,136	9,974
Accrued payroll and employee benefits		75,148	67,381	10,815
Other current liabilities	11	490,679	404,222	64,882
<b>Total current liabilities</b>		<b>1,462,547</b>	<b>1,209,518</b>	<b>194,141</b>
Long-term borrowings	9		2,000	321
Deferred tax liabilities	10(d)	46,248	56,120	9,008
Other liabilities	10(b)	31,625	32,657	5,242
<b>Total liabilities</b>		<b>1,540,420</b>	<b>1,300,295</b>	<b>208,712</b>
<b>Equity</b>				
Ordinary shares:				
Par value: US\$0.01				
Authorized: 500,000,000 shares				
Issued and outstanding:				
2011: 105,740,648				
2012: 101,410,422	18	8,532	8,258	1,326
Additional paid-in capital		954,750	853,551	137,004
Accumulated other comprehensive loss		(104,608)	(104,147)	(16,717)

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Retained earnings	1,197,507	1,254,464	201,355
<b>Total equity attributable to Simcere Pharmaceutical Group</b>	<b>2,056,181</b>	<b>2,012,126</b>	<b>322,968</b>
Non-controlling interest	137,516	60,242	9,670
<b>Total shareholders equity</b>	<b>2,193,697</b>	<b>2,072,368</b>	<b>332,638</b>
Commitments and contingencies	14		
<b>Total liabilities and shareholders equity</b>	<b>3,734,117</b>	<b>3,372,663</b>	<b>541,350</b>

See accompanying notes to consolidated financial statements.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Consolidated Statements of Comprehensive Income**

(Amounts expressed in thousands, except share data)

	Note	Year ended December 31,			
		2010 RMB	2011 RMB	2012 RMB	2012 US\$
Revenue	16 and 19	2,141,098	2,040,547	2,082,966	334,339
Cost of materials and production		(341,787)	(328,159)	(361,071)	(57,956)
<b>Gross profit</b>		<b>1,799,311</b>	<b>1,712,388</b>	<b>1,721,895</b>	<b>276,383</b>
<i>Operating expenses and other operating income:</i>					
Research and development		(125,737)	(198,722)	(228,717)	(36,711)
Sales, marketing and distribution		(1,186,144)	(1,131,974)	(1,140,810)	(183,113)
General and administrative		(269,512)	(288,144)	(255,999)	(41,091)
Impairment charges	1(c),7(d) and 7(e)			(97,247)	(15,609)
Gain arising from loss of control of a subsidiary	7(a)			24,789	3,979
Other operating income	7(e)		50,000	15,650	2,512
<b>Income from operations</b>		<b>217,918</b>	<b>143,548</b>	<b>39,561</b>	<b>6,350</b>
Interest income		4,214	4,676	4,066	653
Interest expense	5	(19,920)	(42,342)	(69,258)	(11,117)
Foreign currency exchange gains (losses), net		5,511	7,732	(923)	(148)
Other income		2,286	15,036	11,429	1,834
Losses of equity method affiliated company		(14,716)	(12,192)	(4,859)	(780)
<b>Earnings (losses) before income taxes</b>		<b>195,293</b>	<b>116,458</b>	<b>(19,984)</b>	<b>(3,208)</b>
Income tax benefit (expense)	10	(10,640)	35,371	5,581	896
<b>Net income (loss)</b>		<b>184,653</b>	<b>151,829</b>	<b>(14,403)</b>	<b>(2,312)</b>
Net income attributable to redeemable non-controlling interest		(1,776)	(1,378)		
Net loss (income) attributable to other non-controlling interest		(10,466)	27,938	71,360	11,454
<b>Net income attributable to Simcere Pharmaceutical Group shareholders</b>		<b>172,411</b>	<b>178,389</b>	<b>56,957</b>	<b>9,142</b>
<b>Earnings per share:</b>	15				
Basic		1.59	1.63	0.53	0.09
Diluted		1.55	1.61	0.53	0.09
<b>Net income (loss)</b>		<b>184,653</b>	<b>151,829</b>	<b>(14,403)</b>	<b>(2,312)</b>
<b>Other comprehensive income (loss)</b>					
Net effect of foreign currency translation, net of nil tax		(5,964)	(7,096)	461	74
<b>Comprehensive income (loss)</b>		<b>178,689</b>	<b>144,733</b>	<b>(13,942)</b>	<b>(2,238)</b>
Comprehensive income attributable to redeemable non-controlling interest		(1,776)	(1,378)		
Comprehensive loss (income) attributable to other non-controlling interest		(10,466)	27,938	71,360	11,454
<b>Comprehensive income attributable to Simcere Pharmaceutical Group shareholders</b>		<b>166,447</b>	<b>171,293</b>	<b>57,418</b>	<b>9,216</b>



See accompanying notes to consolidated financial statements.

F-4

---

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Consolidated Statements of Changes in Shareholders' Equity**

(Amounts expressed in thousands, except share data)

	Note	Number of ordinary shares	Par value RMB	Additional paid-in capital RMB	Accumulated other comprehensive loss RMB	Retained earnings RMB	Equity attributable to Simcere Pharmaceutical Group RMB	Non- controlling interests RMB	Total shareholders equity (note 12) RMB
<b>Balance as of January 1, 2010</b>		<b>110,534,932</b>	<b>8,851</b>	<b>1,218,214</b>	<b>(91,548)</b>	<b>846,707</b>	<b>1,982,224</b>	<b>225,459</b>	<b>2,207,683</b>
Share-based compensation	17			31,099			31,099		31,099
Issuance of ordinary shares upon exercise of non-vested shares	17	518,322	35				35		35
Repurchase and retirement of ordinary shares	18	(4,263,732)	(289)	(127,210)			(127,499)		(127,499)
Net income						172,411	172,411	10,466	182,877
Other comprehensive income					(5,964)		(5,964)		(5,964)
Acquisition of Nanjing Tung Chit shares from non-controlling interests	7(c)			(6,019)			(6,019)	(261)	(6,280)
Acquisition of Jilin Boda shares from non-controlling interests	7(c)			(126,110)			(126,110)	(48,075)	(174,185)
Dividend declared by subsidiary to non-controlling interest								(7,846)	(7,846)
Deemed acquisition of redeemable non-controlling interest in Jilin Boda	7(b)			(41,505)			(41,505)	(4,172)	(45,677)
<b>Balance as of December 31, 2010</b>		<b>106,789,522</b>	<b>8,597</b>	<b>948,469</b>	<b>(97,512)</b>	<b>1,019,118</b>	<b>1,878,672</b>	<b>175,571</b>	<b>2,054,243</b>
Share-based compensation	17			29,341			29,341		29,341
Issuance of ordinary shares upon exercise of non-vested shares and share options	17	244,670	16	23			39		39
Repurchase and retirement of ordinary shares	18	(1,293,544)	(81)	(31,874)			(31,955)		(31,955)
Net income (loss)						178,389	178,389	(27,938)	150,451
Other comprehensive income					(7,096)		(7,096)		(7,096)
Dividend declared by subsidiary to non-controlling interest	7(b)			8,791			8,791	(10,117)	(10,117)

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Acquisition of  
Redeemable  
non-controlling interest in  
Jilin Boda

<b>Balance as of December 31, 2011</b>		<b>105,740,648</b>	<b>8,532</b>	<b>954,750</b>	<b>(104,608)</b>	<b>1,197,507</b>	<b>2,056,181</b>	<b>137,516</b>	<b>2,193,697</b>
Share-based compensation	17			20,437			20,437		20,437
Issuance of ordinary shares upon exercise of non-vested shares and share options	17	213,388	13				13		13
Repurchase and retirement of ordinary shares	18	(4,543,614)	(287)	(121,636)			(121,923)		(121,923)
Net income (loss)						56,957	56,957	(71,360)	(14,403)
Other comprehensive income					461		461		461
Dividend declared by subsidiary to non-controlling interest								(6,514)	(6,514)
Capital injection to a newly established subsidiary								600	600
<b>Balance as of December 31, 2012</b>		<b>101,410,422</b>	<b>8,258</b>	<b>853,551</b>	<b>(104,147)</b>	<b>1,254,464</b>	<b>2,012,126</b>	<b>60,242</b>	<b>2,072,368</b>
<b>Balance as of December 31, 2012 - US\$</b>			<b>1,326</b>	<b>137,004</b>	<b>(16,717)</b>	<b>201,355</b>	<b>322,968</b>	<b>9,670</b>	<b>332,638</b>

See accompanying notes to consolidated financial statements.

Table of Contents

## Simcere Pharmaceutical Group and Subsidiaries

## Consolidated Statements of Cash Flows

(Amounts expressed in thousands)

	Note	2010 RMB	Year ended December 31,		2012 US\$
			2011 RMB	2012 RMB	
<b>Operating activities:</b>					
Net income (loss)		184,653	151,829	(14,403)	(2,312)
<i>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</i>					
Bad debt expense (reversal)	3	843	994	(618)	(99)
Inventory write-downs	4	4,846	3,205		
Depreciation of property, plant and equipment	5	76,976	85,319	95,175	15,277
Amortization of intangible assets	7(d)	37,128	33,731	33,206	5,330
Land use right expense		3,203	3,203	3,203	514
Impairment charges	1(c),7(d) and 7(e)			97,247	15,609
Losses of equity method affiliated companies		14,716	12,192	4,859	780
Loss (gain) on disposals of property, plant and equipment		(1,463)	636	2,792	448
Gain arising from loss of control of a subsidiary	7(a)			(24,789)	(3,979)
Deferred tax benefit	10(a)	(27,722)	(66,208)	(41,487)	(6,659)
Share-based compensation	17	31,099	29,341	20,437	3,280
Unrealized foreign currency exchange losses (gains)		(4,742)	(5,489)	515	83
<i>Changes in assets and liabilities, net of effects from acquisitions</i>					
Accounts and bills receivable		(181,260)	(393,128)	184,379	29,595
Inventories		12,077	(40,181)	5,776	927
Other current assets		(950)	(14,672)	(890)	(143)
Amounts due from related parties		1,443	(815)	2,909	467
Accounts and bills payables		(102,611)	30,932	(18,434)	(2,959)
Accrued payroll and employee benefits		4,891	19,589	(7,767)	(1,247)
Unrealized profit of inventory sold to an affiliated company				1,515	243
Other current liabilities and other liabilities		79,023	(27,261)	(31,284)	(5,021)
Amounts due to related parties		110	(110)	1,237	199
<b>Net cash provided by (used in) operating activities</b>		<b>132,260</b>	<b>(176,893)</b>	<b>313,578</b>	<b>50,333</b>

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Consolidated Statements of Cash Flows**

(Amounts expressed in thousands)

	Note	2010 RMB	Year ended December 31,		2012 US\$
			2011 RMB	2012 RMB	
<b>Investing activities:</b>					
Payment for purchase of property, plant and equipment and intangible assets		(188,828)	(164,255)	(73,349)	(11,773)
Decrease (increase) in deposits for purchase of land use rights			(52,390)	19,390	3,112
Proceeds from disposal of property, plant and equipment and land use right			18,365		
Payments for acquisition of subsidiaries, net of cash acquired		(9,830)		(12,772)	(2,050)
Payment for establishment of an affiliated company	7(a)			(28,211)	(4,528)
Decrease (increase) in pledged bank deposits		10,524	(47,574)	29,313	4,705
Advance received (made to) from an affiliated company	19	(14,071)	17,673		
<b>Net cash used in investing activities</b>		<b>(202,205)</b>	<b>(228,181)</b>	<b>(65,629)</b>	<b>(10,534)</b>
<b>Financing activities:</b>					
Proceeds from exercise of non-vested shares and share options		35	39	13	2
Payment for repurchase and retirement of ordinary shares	18	(127,499)	(31,955)	(121,923)	(19,570)
Proceeds from short term bank loans and other borrowings		350,000	918,150	1,113,679	178,758
Principal repayments of bank loans and other borrowings		(170,000)	(481,306)	(1,252,050)	(200,968)
Payment for acquisition of additional non-controlling interest		(150,274)	(52,805)	(13,388)	(2,149)
Payment from non-controlling interest for capital injection to a newly established subsidiary				600	96
Payment of dividends to the non-controlling interest			(9,175)	(6,514)	(1,045)
<b>Net cash (used in) provided by financing activities</b>		<b>(97,738)</b>	<b>342,948</b>	<b>(279,583)</b>	<b>(44,876)</b>

See accompanying notes to consolidated financial statements.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Consolidated Statements of Cash Flows**

(Amounts expressed in thousands)

	Note	2010 RMB	Year ended December 31, 2011 RMB	2012 RMB	2012 US\$
Effect of exchange rate changes on cash		(1,222)	(1,607)	(54)	(9)
Net decrease in cash		(168,905)	(63,733)	(31,688)	(5,086)
Cash at beginning of year		442,488	273,583	209,850	33,683
Cash at end of year		273,583	209,850	178,162	28,597
<b>(a) Supplemental cash flow and non-cash information:</b>					
<b>Cash paid during the period for:</b>					
Income taxes		37,528	48,393	29,186	4,685
Interest, net of capitalized interest	5	19,920	42,342	69,258	11,117
<b>Non-cash investing and financing transactions:</b>					
Payable and accruals for acquisition of property, plant and equipment, land use right and intangible assets		78,791	78,546	39,829	6,393
Payable for acquisition of Jiangsu Quanyi	11(b)	29,875	28,422		
Payable for acquisition of non-controlling interest of Jilin Boda	11(b)	26,153	13,388		
Assets transfer out for acquisition of Jilin Boda	7(c)	4,038			
Gain arising from loss of control of Shanghai Simcere	7(a)			24,789	3,979
<b>(b) Analysis of net cash outflow in respect of acquisitions is as follow:</b>					
<b>i) Acquisition of Shandong Simcere in 2006</b>					
Cash consideration paid		(9,830)			
<b>ii) Acquisition of Jiangsu Quanyi in 2009</b>					
Cash consideration paid				(12,772)	(2,050)

See accompanying notes to consolidated financial statements

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

**1 Principal activities, significant concentrations and risks, and basis of presentation**

(a) *Principal activities*

Simcere Pharmaceutical Group (the Company) and its subsidiaries (collectively the Group), are principally engaged in the research, development, manufacture and distribution of pharmaceutical and vaccine products in the People's Republic of China (the PRC).

(b) *Significant concentrations and risks*

*Revenue concentrations*

The Group sells its products to pharmaceutical distributors and the PRC government. Sales to distributors account for substantially all of the Group's revenues. The Group does not have long-term distribution agreements and competes for desired distributors with other pharmaceutical and vaccine manufacturers. Consequently, maintaining relationships with existing distributors and replacing distributors may be costly, difficult and time-consuming. Any disruption of the Group's distribution network, including the failure to renew existing distribution agreements with desired distributors, could negatively affect the Group's ability to effectively sell its products and could materially and adversely affect its business, financial condition and results of operations. As of and for the years ended December 31, 2010, 2011 and 2012, no single customer contributed 10% or more of the Group's total revenues or accounts and bills receivable. For the years ended December 31, 2010, 2011 and 2012, sales to five largest customers accounted in aggregate for approximately 17.6%, 17.2% and 16.6% of the Group's total revenues, respectively.

The Group derives a substantial portion of revenue from the sales of five products, namely Bicun, Zailin, Yingtaiqing, Sinofuan and Endu. Each of these products individually contributed to revenues of over RMB100,000 (US\$16,051) for the year ended December 31, 2012. Total revenues of these five products accounted for 71.9%, 72.2% and 69.6% of the Group's revenue for the years ended December 31, 2010, 2011 and 2012, respectively. All of these five products except Endu were subject to the price controls described below, which accounted for 61.4%, 59.3% and 56.5% of the Group's revenue for the years ended December 31, 2010, 2011 and 2012, respectively. The Group expects the sales of these five products to continue to comprise a substantial portion of revenues in the future; accordingly any factors adversely affecting the sales of any of these five products will have a material adverse effect on the Group's business, financial condition and results of operations.

*Price control by PRC government authorities*

The retail prices of certain pharmaceuticals sold in China are subject to price controls in the form of fixed prices or price ceilings. Pharmaceuticals subject to price control include pharmaceuticals identified in (i) China's national essential drug list and drug reimbursement list issued by China's Ministry of Human Resources and Social Security; (ii) the provincial medical insurance catalogs issued by the provincial Ministry of Human Resources and Social Security; and (iii) those pharmaceuticals whose production or trading are deemed to constitute monopolies.

Manufacturers and distributors cannot set the retail price for any given price-controlled product above the price ceilings or deviate from fixed price imposed by the government. The prices of medicines that are not subject to price controls are determined freely, subject to notification to the provincial pricing authorities.

Certain of the Group's products are subject to such price controls and accordingly, the price of such products can not be increased at the Group's discretion above the relevant controlled price ceiling without prior governmental approval. In addition, the price of such products may also be adjusted downward by the relevant government authorities in the future. Such price control, especially downward price adjustment, may negatively affect the Group's revenue and profitability. For the years ended December 31, 2010, 2011 and 2012 73%, 82% and 85% respectively, of the Group's revenue were from products that were subject to government pricing controls.



Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

*Concentration of suppliers*

The Group sources raw materials, as well as packaging materials, from various suppliers in the PRC. Historically, the majority of the Group's raw materials have been readily available. The Group generally maintains two vendors for each major raw material in order to diversify its vendor base and to ensure a reliable supply of raw materials at reasonable prices.

In addition, the Group also purchased two pharmaceutical products from third party suppliers and is the exclusive distributor of the two pharmaceutical products. The revenue of the two pharmaceutical products accounted for 10.0%, 11.2% and 9.7% of the Group's revenue for the years ended December 31, 2010, 2011 and 2012, respectively.

For the years ended December 31, 2010, 2011 and 2012, the Group purchased 36.9%, 37.0% and 31.5%, respectively, of its total supply of raw materials and pharmaceutical products from its five largest suppliers and purchased 17.3%, 19.7% and 13.6% of its total supply of raw materials and pharmaceutical products from its largest supplier.

(c) ***Basis of presentation***

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( U.S. GAAP ).

On December 21, 2012, the Group signed an agreement with Changzhou Diaozhuang Industrial Co., Ltd ( Diaozhuang Industrial ), for the sale of certain assets, including certain plant, machineries and land use right held by Jiangsu Quanyi Biological Technology Stock Co., Ltd. ( Jiangsu Quanyi ) for a cash consideration of RMB25,514 (US\$4,095). As of December 31, 2012, the above property, plant and equipment, land use right were classified as assets held for sale. The Group recognized an impairment loss of RMB1,831 (US\$294) in the consolidated statements of comprehensive income for the year ended December 31, 2012, representing the difference between the carrying amount of these assets of RMB27,345 (US\$4,389) and fair value less cost to sell of RMB25,514 (US\$4,095).

The Group previously accounted for its investment in Shanghai Celgen Bio-Pharmaceutical Co., Ltd. ( Shanghai Celgen ) under the equity method of accounting and included the investment in the line item Investments in and advances to affiliated companies in the Group's consolidated balance sheet as of December 31, 2011 and 2010. As of December 31, 2012, management approved a plan to sell the investment in Shanghai Celgen. On January 15, 2013, the Group signed a share transfer agreement with Devont Asset Management Limited ( Devont ) to

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

transfer its Shanghai Celgen for a cash consideration of RMB302 million. Upon completion of the transaction, the Group will no longer hold any equity interest in Shanghai Celgen. As of December 31, 2012, the carrying amount of investment in Shanghai Celgen of RMB65,036 (US\$10,439) was classified as assets held for sale. As of the issuance date of the financial statements, the sales of Shanghai Celgen has yet to be completed and the cash consideration of RMB302,000 has not been received by the Group.

### **2**                      **Summary of significant accounting policies**

#### (a)                      *Consolidation*

The accompanying consolidated financial statements include the financial statements of the Company and its majority owned subsidiaries. For consolidated subsidiaries where the Company's ownership is less than 100%, the outside shareholders' interests are shown as non-controlling interest. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has no involvement with variable interest entities. The Company accounts for investments over which it has significant influence but not a controlling financial interest using the equity method of accounting.

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

(b) *Use of estimates*

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management of the Group to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates and assumptions include recoverability of the carrying amount of property, plant and equipment, goodwill, intangible assets (including acquired in-process research and development (IPR&D)) and investments in an affiliated company; the allocation of the purchase price for the Group's business acquisitions; allowances for doubtful receivables and deferred tax assets; depreciation and amortization lives; realizability of inventories; and amounts recognized for contingencies. These estimates are often based on complex judgments and assumptions that management believes to be reasonable but are inherently uncertain and unpredictable. Actual results could differ from those estimates.

(c) *Foreign currency transactions and translation*

The reporting currency of the Group is the Renminbi (RMB).

The functional currency of the Company's PRC subsidiaries is the RMB. RMB is not a fully convertible currency. All foreign exchange transactions involving RMB must take place either through the People's Bank of China (PBOC) or other institutions authorized to buy and sell foreign exchange. The exchange rates adopted for the foreign exchange transactions are the rates of exchange quoted by the PBOC.

Transactions dominated in currencies other than the functional currency are translated into the functional currency at the exchange rate at the date of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the applicable exchange rate at the balance sheet date. The resulting exchange differences are recognized in the consolidated statements of comprehensive income.

Assets and liabilities of subsidiaries, whose functional currency is not the RMB, are translated into RMB at the exchange rate at the balance sheet date. Income and expense items are translated into RMB at the average rates of exchange prevailing during the period. The adjustment resulting from translating the financial statements of such entities is reflected as a component of accumulated other comprehensive loss within shareholders' equity.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

For the convenience of the readers, the December 31, 2012 RMB amounts included in the accompanying consolidated financial statements have been translated into U.S. dollars at the rate of US\$1.00=RMB6.2301, being the noon buying rate for U.S. dollars in the City of New York on December 31, 2012 for cable transfers in RMB per U.S. dollar as certified for customs purposes by the Federal Reserve Bank of New York. No representation is made that the RMB amounts could have been, or could be, converted into U.S. dollars at that rate or at any other rate on December 31, 2012 or at any other date.

(d) ***Cash and pledged bank deposits***

Cash consist of cash on hand, cash in bank accounts and interest-bearing savings accounts.

As of December 31, 2011 and 2012, RMB193,779 and RMB164,849 (US\$26,460), respectively, in cash was held in major financial institutions located in the PRC. Management believes that these financial institutions have high credit rating.

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

Cash that is restricted as to withdrawal for use or pledged as security is disclosed separately on the face of the balance sheet, and is not included in the cash total in the consolidated statements of cash flows. The pledged bank deposits are also held in major financial institutions located in the PRC and include cash received from the National Finance Bureau which is restricted for use for R&D projects conducted by the Group. Any withdrawal of funds from the account requires an approval from the National Finance Bureau. The pledged bank deposits also include cash maintained at a bank as security for short-term bills payable and letters of credit issued by the subsidiaries of the Company to third party suppliers. Bank deposits are restricted as to withdrawal or use by the subsidiaries as long as the related short-term bills payable have not been settled. Upon maturity of the bills payable which generally ranges from three to six months, the cash is available for use by the Group.

(e) ***Accounts receivable and bills receivable***

Accounts and bills receivable are recognized at the invoiced amount and do not bear interest. Amounts collected on accounts and bills receivable are included in net cash provided by operating activities in the consolidated statements of cash flows. The Group maintains an allowance for doubtful accounts for estimated losses inherent in its accounts receivable portfolio. In establishing the required allowance, management considers historical losses adjusted to take into account current market conditions and our customers' financial condition, the amount of receivables in dispute, and the current receivables aging and current payment patterns. The Company reviews its allowance for doubtful accounts monthly. Past due balances over 180 days and over a specified amount are reviewed individually for collectability. All other balances are reviewed on a pooled basis. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Write-offs for 2010, 2011 and 2012 approximated RMB117, RMB1,180 and nil, respectively. The Company does not have any off-balance-sheet credit exposure related to its customers.

To reduce the Group's credit risk, the Group has required certain customers to pay for the sale of the Group's products by bills receivable. A bill receivable primarily represents a short-term note receivable issued by a financial institution that entitles the Group to receive the full face amount from the financial institution at maturity, which generally ranges from three to six months from the date of issuance. Historically, the Group has not experienced any collection losses on bills receivable and therefore no allowance for doubtful accounts has been provided. Apart from those disclosed in note 14(d), the Group does not have any off-balance-sheet credit exposure related to bills receivable.

(f) ***Inventories***

Inventories are stated at the lower of cost or market value. Cost is determined using the weighted average cost method. Costs of work-in-progress and finished goods comprise direct materials, direct labor and related manufacturing overhead based on normal operating capacity.

(g) *Investment in and advances to an affiliated company*

An investment in an entity where the Group does not have a controlling financial interest, but has the ability to exercise significant influence over the operating and financial policies of the investee, is accounted for using the equity method of accounting. Under the equity method of accounting, the Group's share of the investee's results of operations is included in the consolidated statements of income.

The Group recognizes a loss when there is a loss in value of an equity method investment which is other than a temporary decline. The process of assessing and determining whether an impairment on a particular equity investment is other than temporary requires a significant amount of judgment. To determine whether an impairment is other-than-temporary, management considers whether the Group has the ability and intent to hold the investment until recovery and whether evidence indicating the carrying value of the investment is recoverable outweighs evidence to the contrary. Evidence considered in this assessment includes the reasons for the impairment, the severity and duration of the decline in value, any change in value subsequent to year end, and forecasted performance of the investee. There was no impairment charges related to the investment in the affiliated companies for any of the years presented.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****(h) Long-lived assets***Property, plant and equipment*

Property, plant, and equipment are stated at cost. Depreciation is provided over the estimated useful lives of the assets, using the straight-line method. When items are retired or otherwise disposed of, income is charged or credited for the difference between net book value and proceeds realized thereon. Ordinary maintenance and repairs are charged to expense as incurred, and replacements and betterments are capitalized. The estimated useful lives of property, plant and equipment are as follows:

Building and leasehold improvements	20 - 50 years
Machinery and equipment	3 - 10 years
Motor vehicles	3 - 8 years
Furniture, fixtures and office equipment	3 - 5 years

No depreciation expense is provided in respect of construction-in-progress.

Depreciation of property, plant and equipment attributable to manufacturing activities is capitalized as part of the cost of inventory, and expensed to cost of materials and production when the inventory is sold.

*Intangible assets with definite lives*

Intangible assets with definite lives are amortized on a straight-line basis over the estimated useful lives of the respective assets. The Group's intangible assets and their respective estimated useful lives are as follows:

Customer relationships	4 - 11 years
Developed technology	7 - 16 years
Product trademarks	6 - 10 years
Manufacturing and supply licenses	1 - 5 years

*Impairment of property plant, and equipment and intangible assets with definitive lives*

Long-lived assets including property, plant and equipment, and intangible assets with definitive lives are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of carrying amount or fair value less costs to sell, and are no longer depreciated. No impairment loss of property, plant and equipment or intangible assets with definite lives was recognized in 2010, 2011 and 2012.

*Indefinite-lived intangible assets*

IPR&D represents the fair value assigned to incomplete research projects that the Group acquires through business combinations, which at the time of acquisition, have not reached technological feasibility. For business combinations for which the acquisition date is before January 1, 2009, the fair value of IPR&D projects was expensed upon acquisition. For acquisition date that is on or after January 1, 2009, the fair value of IPR&D projects is recognized as intangible asset on the consolidated balance sheet rather than expensed. The amounts capitalized are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Group makes a determination as to the useful life of the intangible asset and begins amortization.



Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

The Group tests indefinite-lived intangibles, including IPR&D, for impairment at least annually, and more frequently if an event occurs or circumstances change that indicate impairments might exist. The impairment test consists of a comparison of the fair value of the IPR&D with its carrying amount. If the carrying amount of an IPR&D exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. For the year ended December 31, 2012, the Group recognized an impairment loss on IPR&D of RMB70,100 (US\$11,252). No impairment loss of IPR&D was recognized in 2010 and 2011.

*Goodwill*

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. Goodwill is not amortized but instead goodwill is reviewed for impairment at least annually, and more frequently if events and circumstances indicate that the asset might be impaired. This determination is made at the reporting unit level. In September 2011, the FASB issued revised guidance on *Testing of Goodwill for Impairment*. The revised guidance specifies that an entity has the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. An entity can choose to perform the qualitative assessment on none, some or all of its reporting units. Moreover, an entity can bypass the qualitative assessment for any reporting unit in any period and proceed directly to step one of the impairment test, and then resume performing the qualitative assessment in any subsequent period. The revised guidance was effective to both public and nonpublic entities that have goodwill reported in their financial statements during interim and annual periods beginning after December 15, 2011. The Group adopted the revised guidance in 2012. If a qualitative assessment is not performed, or if as a result of a qualitative assessment it is not more likely than not that the fair value of a reporting unit exceeds its carrying value, then the two-steps impairment test is performed. The first step of the impairment test involves comparing the fair value of the reporting unit with its carrying amount, including goodwill. Second, if the carrying amount of a reporting unit exceeds its fair value, an impairment loss is recognized for any excess of the carrying amount of the reporting unit's goodwill over the implied fair value of that goodwill. The implied fair value of goodwill is determined by allocating the fair value of the reporting unit in a manner similar to a purchase price allocation. The residual fair value after this allocation is the implied fair value of the reporting unit goodwill.

Management evaluated and determined that there are two components below the Group's operating segment: the pharmaceutical business and the vaccines business. The pharmaceutical business and vaccines business have dissimilar economic characteristics and they each manufacture, distribute and sell distinct products which require different technologies and marketing strategies. As such, management determined that the Group has two reporting units, a pharmaceutical reporting unit and a vaccine reporting unit, for goodwill impairment testing for the years ended December 31, 2010, 2011 and 2012. The Group used a discounted cash flow analysis to determine the fair value of its reporting units. For the year ended December 31, 2012, the Group recognized an impairment loss on goodwill of RMB25,316 (US\$4,063) in connection with vaccine reporting unit. No impairment loss of goodwill was recognized in 2010 and 2011.

(i) *Land use rights*

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

A land use right in the PRC represents an exclusive right to occupy, use, develop, lease, transfer a piece of land during the contractual term of the land use right. Land use rights are usually paid in one lump sum at the date the right is granted. The payment usually covers the entire duration period of the land use right. The lump sum advance payments are capitalized as land use right assets and then charged to expenses on a straight-line basis over the respective periods of the rights of 24-75 years.

F-14

---

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

(j) ***Income taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax loss and tax credit carryforwards. A valuation allowance is provided to reduce the amount of deferred tax assets if it is considered more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in consolidated statements of income in the period that includes the enactment date.

The Company's management determines whether it is more likely than not that a tax position will be sustained upon examination, based solely on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, it is presumed that the position will be examined by the appropriate taxing authority that has full knowledge of all relevant information. In addition, a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. A recognized income tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized. The tax positions are regularly reevaluated based on the results of the examination of income tax filings, statute of limitations expirations and changes in tax law that would either increase or decrease the technical merits of a position relative to the more-likely-than-not recognition threshold. The Group's policy is to accrue interest and penalties related to unrecognized tax benefits as a component of income tax expense.

(k) ***Revenues***

Sales of pharmaceutical and vaccine products represent the invoiced value of products sold. Value added taxes (VAT) collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from revenues in the consolidated statements of comprehensive income.

The Group recognizes revenue from the sale of products when the following criteria are met: 1) persuasive evidence of an arrangement exists (sales agreements and customer purchase orders are used to provide evidence of the existence of an arrangement); 2) delivery of the product has occurred and risks and benefits of ownership have been transferred, which is when the product is received by the customer at its or a designated location in accordance with the sales terms (the customer's written acknowledgement of the receipt of the product provides evidence of delivery); 3) the sales price is fixed or determinable; and 4) collectability is reasonably assured. The Group's sales agreements do not provide the customer the right of return, unless the product is defective in which case the Group allows for an exchange of product or return. For the periods presented, defective product returns were immaterial.

(1) *Government grants*

Government grants are recognized when there is reasonable assurance that the Group will comply with the conditions attaching to them and the grants are receivable. Grants that compensate research and development expenses are recognized as a reduction to the related research and development expenses. Grants that compensate the Group for the cost of property, plant and equipment and land use rights are recognized as a reduction of the cost of the related asset and are recognized over the useful life of the asset by way of reduced depreciation expense or lease expense.

For the years ended December 31, 2010, 2011 and 2012, government grants of RMB5,755, RMB24,796 and RMB16,846 (US\$2,704), respectively, have been recognized as a reduction of research and development expenses.

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

(m) ***Research and development***

Research and development costs are expensed as incurred. These expenses include the costs of the Group's internal research and development activities and the costs of research and development conducted by others on behalf of the Group, such as through third-party collaboration arrangements. Research and development costs in connection with third-party collaboration arrangements prior to regulatory approval are expensed when the research and development activities are performed. Once a regulatory approval is obtained, subsequent payments are recognized as intangible assets and, unless the assets are determined to have an indefinite life, amortized over the remaining agreement terms or the expected product life cycle, whichever is shorter.

The costs of acquired technology know-how (drugs in a development stage) that are purchased from others for a particular research and development project either individually, or as part of a group of assets, and that have no alternative future uses (in other research and development projects or otherwise), are expensed as research and development costs. Management has determined that for an acquired technology know-how to have an alternative future use, it should be (a) reasonably expected that the Group will use the technology in an alternative manner for an economic benefit and (b) the Group's use of the technology is not contingent on further development subsequent to acquisition (that is, it can be used in an alternative manner at the acquisition date).

(n) ***Advertising costs***

Advertising costs are expensed as incurred and included in sales, marketing and distribution expenses. Advertising costs for the years ended December 31, 2010, 2011 and 2012 amounted to RMB106,708, RMB83,824 and RMB55,033 (US\$8,833), respectively.

(o) ***Shipping and handling costs***

Costs incurred by the Group for shipping and handling to transport and deliver products to customers, are included in sales, marketing and distribution expenses. Shipping and handling costs for the years ended December 31, 2010, 2011 and 2012 amounted to RMB16,339, RMB14,940 and RMB14,962 (US\$2,402), respectively. Shipping and other transportation costs are not charged to customers.

(p) ***Retirement and other postretirement benefits***

Contributions to defined contribution retirement plans are charged to the consolidated statements of comprehensive income as and when the related employee service is provided. The Group does not have any defined benefit retirement plans.

(q) *Share-based payment*

The Company recognizes all employee share-based compensation as a cost in the consolidated financial statements. Equity-classified awards are measured at the grant date fair value of the award. The Company estimates grant date fair value using the Black-Scholes-Merton option-pricing model. The Group recognizes the cost of share-based compensation on a straight-line basis over the requisite service period. Share-based compensation cost that has been included in income from operations amounted to RMB31,099, RMB29,341 and RMB20,437 (US\$3,280) for the years ended December 31, 2010, 2011 and 2012, respectively.

(r) *Commitments and contingencies*

In the normal course of business, the Group is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability. The Group records accruals for such loss contingencies when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. Historically, the Group has experienced no material product liability claims.

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

(s) ***Earnings per share***

Basic earnings per share is computed by dividing net income attributable to the Group by the weighted average number of ordinary shares outstanding during the period. Diluted earnings per share is computed by dividing net income attributable to the Group by the weighted average number of ordinary shares and dilutive ordinary equivalent shares outstanding during the period. Dilutive ordinary equivalent shares consist of the ordinary shares issuable upon the exercise of outstanding share options and non-vested shares by applying the treasury stock method. Dilutive ordinary equivalent shares in the diluted earnings per share computation are excluded to the extent that their effect is anti-dilutive.

(t) ***Segment reporting***

For the years ended December 31, 2010, 2011 and 2012, management determined that the Group as a whole is the only operating segment as the Group's chief operating decision maker regularly receives and reviews the financial information on a consolidated group basis for purposes of making decisions about resource allocation and assessing performance. All of the Group's operations and customers are located in the PRC, consequently, no geographic information is presented.

(u) ***Fair value measurement***

The Group utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Group determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.
- Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

In May 2011, the FASB issued ASU 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. The new standard does not extend the use of fair value but, rather, provides guidance about how fair value should be applied where it is already required or permitted under IFRS or U.S. GAAP. For U.S. GAAP, most of the changes are clarifications of existing guidance or wording changes to align with IFRS. The provisions of the ASU are effective for annual or interim reporting periods beginning after December 15, 2011. The Group adopted the provisions of the ASU in 2012. The adoption of ASU 2011-04 did not have a material effect on the Group's consolidated financial statements. See note 21 to the consolidated financial statements.



Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****(v) *Effect of Recent Accounting Pronouncements***

In June 2011, the FASB issued revised guidance on *Presentation of Comprehensive Income*. The revised guidance requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income and eliminates one presentation option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The revised guidance states that an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In a single continuous statement, the entity is required to present the components of net income and total net income, the components of other comprehensive income and a total for other comprehensive income, along with the total of comprehensive income in that statement. In the two-statement approach, an entity is required to present components of net income and total net income in the statements of operations. The statement of other comprehensive income should immediately follow the statements of operations and include the components of other comprehensive income and a total for other comprehensive income, along with a total for comprehensive income. In addition, in December 2011, the FASB issued revised guidance on *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards*. The revised guidance specifies that an entity should defer the changes related to the presentation of reclassification adjustments. The revised guidance is effective for interim or annual periods beginning after December 15, 2011. The Group adopted the revised guidance in 2012 by presenting items of net income and other comprehensive income in one continuous statement, consolidated statements of comprehensive income. The Group did not have any reclassification adjustment for each component of other comprehensive income in the years presented in the consolidated statements of comprehensive income.

In July 2012, the FASB issued revised guidance on *Testing Indefinite-Lived Intangible Assets for Impairment*. The revised guidance permits an entity first to assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test in accordance with Subtopic 350-30, *Intangibles - Goodwill and Other - General Intangibles Other than Goodwill*. An entity also has the option to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to performing the quantitative impairment test. An entity will be able to resume performing the qualitative assessment in any subsequent period. The revised guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The adoption of this guidance is not expected to have a material impact on the Group's consolidated financial statements.

**3 Accounts and bills receivable, net**

Accounts and bills receivable, net are summarized as follows:

	<b>December 31,</b>		
<b>2011</b>	<b>2012</b>		<b>2012</b>
<b>RMB</b>	<b>RMB</b>		<b>US\$</b>

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Accounts receivable due from a related party		29,555	4,744
Accounts receivable due from third parties	469,339	390,597	62,695
Less: allowance for doubtful accounts	(7,289)	(6,671)	(1,071)
<b>Accounts receivable, net</b>	<b>462,050</b>	<b>413,481</b>	<b>66,368</b>
Bills receivable	814,822	679,630	109,088
<b>Total accounts and bills receivable, net</b>	<b>1,276,872</b>	<b>1,093,111</b>	<b>175,456</b>

F-18

---

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)**

The movements of the allowance for doubtful accounts are as follows:

	<b>2010</b>	<b>Year ended December 31,</b>		<b>2012</b>
	<b>RMB</b>	<b>2011</b>	<b>2012</b>	<b>2012</b>
		<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
Beginning allowance for doubtful accounts	6,749	7,475	7,289	1,170
Addition charged to (reversal of) bad debt expense	843	994	(618)	(99)
Write-off of accounts receivable	(117)	(1,180)		
<b>Ending allowance for doubtful accounts</b>	<b>7,475</b>	<b>7,289</b>	<b>6,671</b>	<b>1,071</b>

As part of its ongoing control procedures, management monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Credit terms are normally 30 to 90 days from the date of billing. The Group does not require collateral or other security to support credit sales.

Several subsidiaries of the Company sold bills receivable with recourse to third party financial institutions or endorsed bills receivable with recourse to third party suppliers of raw materials, pharmaceutical products or marketing and promotion services. Under this arrangement, control over the transferred bills receivable is surrendered and the subsidiaries do not retain beneficial interests in the transferred bills receivable. All of the transferred bills receivable were accounted for as sales and derecognized upon transfer.

For the years ended December 31, 2010, 2011 and 2012, the Group received proceeds from the sale of bills receivable to third party financial institutions of RMB991,385, RMB301,519 and RMB860,149 (US\$138,063), respectively. The Group recognized discounts of RMB12,620, RMB7,178 and RMB17,654 (US\$2,834) in respect of bills receivable sold to third party financial institutions for the years ended December 31, 2010, 2011 and 2012, respectively, which have been included in interest expense.

As of December 31, 2012, bills receivable of RMB44,180 (US\$7,091) were pledged to banks as collateral for short-term bank loans of RMB37,770 (US\$6,063).

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Inventories by major categories are summarized as follows:

	2011 RMB	December 31, 2012 RMB	2012 US\$
Raw materials	29,804	29,109	4,672
Consumables and packaging materials	19,224	16,225	2,604
Work-in-progress	12,243	13,018	2,090
Finished goods	65,437	62,580	10,045
<b>Total inventories</b>	<b>126,708</b>	<b>120,932</b>	<b>19,411</b>

Inventory write-downs of RMB4,846, RMB3,205 and nil were recognized in cost of materials and production in the consolidated statements of comprehensive income during the years ended December 31, 2010, 2011 and 2012, respectively.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements**

(Amounts expressed in thousands, except share data)

**5 Property, plant and equipment, net**

Property, plant and equipment, net consist of the following:

	2011 RMB	December 31, 2012 RMB	2012 US\$
Buildings and leasehold improvements	543,317	583,666	93,685
Machinery and equipment	414,470	447,892	71,892
Motor vehicles	43,973	44,683	7,172
Furniture, fixtures and office equipment	86,207	93,331	14,981
Construction-in-progress	194,196	114,953	18,451
	1,282,163	1,284,525	206,181
Less: accumulated depreciation and amortization	(381,417)	(443,893)	(71,250)
	900,746	840,632	134,931
Deposits for purchase of property, plant and equipment	25,069	12,914	2,073
<b>Property, plant and equipment, net</b>	<b>925,815</b>	<b>853,546</b>	<b>137,004</b>

Depreciation expense of property, plant and equipment is allocated to the following expense items:

	2010 RMB	Year ended December 31,		2012 US \$
		2011 RMB	2012 RMB	
Costs of materials and production	32,135	28,526	30,316	4,866
Research and development	14,972	25,222	37,395	6,003
Sales, marketing and distribution	296	302	269	43
General and administrative	29,573	31,269	27,195	4,365
<b>Total depreciation expense</b>	<b>76,976</b>	<b>85,319</b>	<b>95,175</b>	<b>15,277</b>

The Group capitalizes interest cost as a component of the cost of construction in progress. Interest incurred consists of the following:

	2010 RMB	Year ended December 31,		2012 US\$
		2011 RMB	2012 RMB	

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Interest cost capitalized	4,468	2,741	1,672	268
Interest cost charged to income	19,920	42,342	69,258	11,117
<b>Total interest cost incurred</b>	<b>24,388</b>	<b>45,083</b>	<b>70,930</b>	<b>11,385</b>

**6 Land use rights**

Land use rights consist of the following items:

	2011 RMB	December 31, 2012 RMB	2012 US\$
Land use rights:			
- non-current portion	139,707	128,220	20,581
- current portion	3,197	3,024	485
<b>Total land use rights</b>	<b>142,904</b>	<b>131,244</b>	<b>21,066</b>

F-20

---

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****7 Acquisitions, disposal of controlling interest, goodwill and intangible assets****(a) 2012 disposal of controlling interest in connection with establishment of Simcere MSD****Disposal of the controlling interest in Shanghai Simcere Pharmaceutical Co., Ltd ( Shanghai Simcere )**

In May 2012, Simcere Pharmaceutical Co., Ltd. ( Hainan Simcere ), entered into agreement with Merck Sharp & Dohme China Holding Co., Ltd ( MSD China ) to increase the capital injection of Shanghai Simcere Pharmaceutical Co., Ltd ( Shanghai Simcere ) and convert Shanghai Simcere from a wholly owned subsidiary of the Group into an equity joint venture. After the additional capital injection by the Group and MSD China, the Group and MSD China hold 49% and 51% of equity interest in Shanghai Simcere (subsequently renamed as Simcere MSD (Shanghai) Pharmaceutical Co., Ltd or Simcere MSD ), respectively. The Group's equity interest in Shanghai Simcere reduced from 100% to 49% on July 11, 2012. Shanghai Simcere engages in the distribution and promotion of certain cardiovascular drugs in the PRC.

The disposal of controlling interest in Shanghai Simcere was accounted as transfer of a subsidiary that constitutes a business in exchange for an increase in an equity-method investee. The remaining 49% equity interest in Shanghai Simcere was recorded at RMB53,000 (US\$8,507), representing the fair value on the closing date of July 11, 2012. Accordingly, the Company recognised a gain of RMB24,789 (US\$3,979), representing the difference of the fair value of 49% equity interest in Simcere MSD of RMB53,000 and the carrying value of Shanghai Simcere and the capital injection by the Group of RMB28,211 (US\$4,528).

Investment in and advances to affiliate companies consist of the following items:

	2011 RMB	December 31, 2012 RMB	2012 US\$
Investment in and advances to Shanghai Celgen	91,355		
Investment in Simcere MSD		56,785	9,115
<b>Total investment in and advance to affiliate companies</b>	<b>91,355</b>	<b>56,785</b>	<b>9,115</b>

The changes in the carrying amount of investment in and advances to affiliate companies for the years ended December 31, 2011 and 2012 are as follows:

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

	Investment in and advances to Shanghai Celgen	Investment in Simcere MSD	Total
<b>December 31, 2010</b>	<b>121,220</b>		<b>121,220</b>
Interest income from advances to Shanghai Celgen (note 19)	1,827		1,827
Repayment from Shanghai Celgen (note 19)	(19,500)		(19,500)
Equity in losses of Shanghai Celgen	(12,192)		(12,192)
<b>December 31, 2011</b>	<b>91,355</b>		<b>91,355</b>
Interest income from advances to Shanghai Celgen (note 19)	828		828
Equity in losses of Shanghai Celgen	(10,159)		(10,159)
Reclassify the investment in Shanghai Celgen to assets held for sale (note 1(c))	(65,036)		(65,036)
Reclassify the advances to Shanghai Celgen to other current assets (note 19(d))	(16,988)		(16,988)
Investment in Simcere MSD		53,000	53,000
Equity in earnings of Simcere MSD		5,300	5,300
Unrealized profit of inventory sold to Simcere MSD		(1,515)	(1,515)
<b>December 31, 2012</b>		<b>56,785</b>	<b>56,785</b>

F-21



Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****(b) 2011 acquisitions****Acquisition of the redeemable non-controlling interest in Jilin Boda Pharmaceutical Co., Ltd. ( Jilin Boda )**

In June 2010, the Group entered into a series of transactions to: i) acquire approximately 39.19% of the equity interest in Boda through an acquisition of 80% equity interest in Nanjing Xiangao Investments management Co., Ltd. ( Nanjing Xiangao ), an investment holding company which holds 48.99% of the equity interest in Jilin Boda; and ii) acquire the remaining 20% equity interest in Nanjing Xiangao (effectively approximately 9.80% equity interest in Jilin Boda) through a put and call arrangement.

The put and call options are exercisable after 1 year from the date of acquisition of the 39.19% equity interest in Jilin Boda. The exercise prices for the call and the put options of the 9.80% equity interest in Jilin Boda held by Nanjing Xiangao are the same and equal to RMB43,600 plus 9.80% of the net profit attributable to Jilin Boda for the period beginning January 1, 2010 to the date of the exercise. Accordingly, the non-controlling interest was recorded outside of permanent equity as redeemable non-controlling interest on the consolidated balance sheet and initially recorded at the fair value of RMB45,677 on July 4, 2010. The Group recognized RMB41,505 as a reduction to additional paid-in-capital which represented the difference between the fair value and the carrying amount of the non-controlling interest on July 4, 2010. Subsequently, the redeemable non-controlling interest is carried at the higher of (1) the initial carrying amount, increased or decreased for the non-controlling interest's share of net income or loss or (2) the expected redemption value. The change of the carrying amounts of the redeemable non-controlling interest is recognized as net income attributable to redeemable non-controlling interest in the consolidated statements of comprehensive income.

On December 31, 2011, the Group exercised the call option to acquire the remaining 20% equity interest in Nanjing Xiangao for a cash consideration of RMB40,040, being RMB8,791 less than the redemption value. The difference between the redemption value and the carrying amount of the redeemable non-controlling interest was recognized as an addition to the additional paid-in-capital. As a result of the acquisition of the redeemable non-controlling interest, the Group increased its equity interest in Jilin Boda from 90.19% to 99.99%.

	<b>Redeemable Non-controlling Interest RMB</b>
<b>Balance as of December 31, 2010</b>	<b>47,453</b>
Income attributable to the redeemable non-controlling interest	1,378
Acquisition of redeemable non-controlling interest	(48,831)
<b>Balance as of December 31, 2011 and December 31, 2012</b>	

(c) *2010 acquisitions*

**Acquisition of a 14.29% equity interest in Nanjing Tung Chit**

On April 2, 2010, the Group acquired 14.29% equity interest in Nanjing Tung Chit Pharmaceutical Co., Ltd ( Nanjing Tung Chit ) for cash consideration of RMB6,280. As a result of the acquisition of the additional 14.29% equity interest, Nanjing Tung Chit became a wholly owned subsidiary of the Group. The additional purchase of equity interest in Nanjing Tung Chit did not constitute a change in control. The non-controlling interest was reduced by RMB261 and the Group recognized RMB6,019 as a reduction to additional paid-in-capital which represents the difference between the fair value of the consideration and the carrying amount of the 14.29% non-controlling interest acquired as of the purchase date.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements**

(Amounts expressed in thousands, except share data)

**Acquisition of an additional 39.19% equity interest in Jilin Boda**

As described in Note 7(b), the Group acquired 39.19% equity interest in Jilin Boda on July 4, 2010. The additional purchase of equity interest in Jilin Boda did not constitute a change in control. The total purchase consideration was RMB174,185 consisting of i) cash consideration of RMB 170,147 and ii) the difference between the fair value of buildings, machinery and equipment of RMB30,430 transferred to the selling shareholder and RMB 26,392 consideration receivable from the selling shareholder for the transfer of such assets and equity interest. The non-controlling interest was reduced by RMB48,075 upon the completion of this acquisition. The Group recognized RMB126,110 as a reduction to additional paid in capital which represents the difference between the fair value of the consideration and the carrying amount of the 39.19% non-controlling interest acquired as of the purchase date.

(d) *Intangible assets*

The Group's intangible assets related to the Group's acquisitions consisted of the following:

	Amortization period Years	Gross carrying amount RMB	December 31, 2011 Accumulated amortization RMB	Accumulated impairment RMB	Net carrying amount RMB
Customer relationships	4-11	37,418	(29,148)		8,270
Developed technologies	7-16	347,640	(111,354)		236,286
Product trademarks	6-10	4,303	(3,487)		816
Manufacturing and supply licenses	1-5	9,544	(9,544)		
In-process research and development		93,100			93,100
<b>Total intangible assets</b>		<b>492,005</b>	<b>(153,533)</b>		<b>338,472</b>

	Amortization period Years	Gross carrying amount RMB	December 31, 2012 Accumulated amortization RMB	Accumulated impairment RMB	Net carrying amount RMB
Customer relationships	4-11	37,418	(33,533)		3,885
Developed technologies	7-16	347,188	(139,704)		207,484
Product trademarks	6-10	4,303	(3,958)		345
Manufacturing and supply licenses	1-5	9,544	(9,544)		

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

In-process research and development	93,100		(70,100)	23,000
<b>Total intangible assets</b>	<b>491,553</b>	<b>(186,739)</b>	<b>(70,100)</b>	<b>234,714</b>
<b>Total US\$</b>	<b>78,900</b>	<b>(29,974)</b>	<b>(11,252)</b>	<b>37,674</b>

F-23

---

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)**

Amortization expense of customer relationships is recognized in sales, marketing and distribution and amortization expense for developed technology, product trademarks and manufacturing and supply licenses is recognized in cost of materials and production. The amortization expense for the years ended December 31, 2010, 2011 and 2012 is as follows:

	<b>2010</b>	<b>Year ended December 31,</b>		<b>2012</b>
	<b>RMB</b>	<b>2011</b>	<b>2012</b>	<b>2012</b>
		<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
Costs of materials and production	31,703	28,330	28,821	4,626
Sales, marketing and distribution	5,425	5,401	4,385	704
<b>Total amortization expense</b>	<b>37,128</b>	<b>33,731</b>	<b>33,206</b>	<b>5,330</b>

The estimated amortization expense of the Group's intangible assets with definite lives for the year ended December 31 is as follows:

	<b>RMB</b>
2013	29,988
2014	28,793
2015	28,505
2016	28,139
2017	22,066

The Group performed its annual impairment test on IPR&D on December 31, 2012. Considering the Group's business strategy will focus on pharmaceutical business, the Group reassessed the commercialization of its in-process R&D projects of vaccine business and revised the vaccine business plan. Due to lowered expectation for future sales and profitability of the vaccine products currently under development, the Group recognized an impairment loss of RMB70,100 (US\$11,252) on IPR&D associated with the acquisition of Jiangsu Quanyi in the consolidated statements of comprehensive income.

**(e) Goodwill**

The changes in the carrying amount of goodwill for the years ended December 31, 2011 and 2012 are as follows:

**Year ended December 31,**

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

	2011 RMB	2012 RMB	2012 US\$
<b>Balance at as of January 1</b>			
Gross goodwill	386,334	386,334	62,011
Accumulated impairment losses	(76,398)	(76,398)	(12,263)
Net goodwill as of January 1	309,936	309,936	49,748
<b>Goodwill acquired during the year</b>			
Impairment loss		(25,316)	(4,063)
<b>Balance as of December 31</b>			
Gross goodwill	386,334	386,334	62,011
Accumulated impairment losses	(76,398)	(101,714)	(16,326)
Net goodwill as of December 31	309,936	284,620	45,685

F-24

---

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

In 2009, during the course of the Group's acquisition of the additional 15% equity interest in Jiangsu Quanyi, the SFDA issued a public notice announcing the initiation of a comprehensive investigation into the quality controls on the production of human use rabies vaccines and ordered Jiangsu Quanyi to halt marketing and production of all products, including human use rabies vaccines. Four batches of human use rabies vaccines manufactured by Jiangsu Quanyi between July and October 2008 were found to have quality problems based on preliminary investigation by the SFDA. In May 2010, upon the completion of the SFDA investigation, Jiangsu Quanyi was fined RMB25,638 for sale of substandard human use rabies vaccines; Jiangsu Quanyi was required to bear the cost of patient re-vaccinations of up to RMB23,034; Jiangsu Quanyi had its Good Manufacturing Practice ( GMP ) certificate for the production of human use rabies vaccines revoked and, certain of Jiangsu Quanyi's employees were prohibited to engage in the production and marketing of pharmaceutical products for a period of ten years. Such employees were also subject to a criminal investigation.

As of December 31, 2009, the Group had recognized an accrual of RMB50,300 for the matter described above, representing the penalty of RMB25,638 by Changzhou Food and Drug Administration, RMB23,034 for the cost for re-vaccinations and a penalty of RMB1,628 levied by the People's Court of Tianning district, Changzhou. As of December 31, 2012, RMB45,266 (US\$7,266) of the penalty and cost for re-vaccinations was paid and the remaining balance of RMB5,034 (US\$808) was included in other current liabilities. Management determined that the contingency that existed at December 31, 2009, being the SFDA investigation which was based on events and facts and circumstances that existed at the acquisition date, and the resolution of the contingency subsequent to December 31, 2009 provided an indication that the fair value of the reporting unit was below its carrying amount as of December 31, 2009.

Therefore, management performed impairment testing for the goodwill of the vaccines reporting unit as of December 31, 2009. Based on such impairment testing, the carrying amount of the vaccine reporting unit as of December 31, 2009 was greater than the fair value of the vaccine reporting unit as determined using the present value of expected future cash flows, and the carrying amount of the vaccine reporting unit goodwill as of December 31, 2009 exceeded the implied fair value of that goodwill. As a result, the Group recognized a goodwill impairment charge of RMB76,398 as of December 31, 2009 to reduce the vaccine reporting unit goodwill to its implied fair value.

On January 24, 2011, the criminal investigation of Jiangsu Quanyi in respect of sale of substandard human use rabies vaccines was completed. According to the final judgment by the Intermediate People's Court of Changzhou City, Jiangsu Province, in addition to the RMB50,300 described above, a penalty of RMB3,000 was imposed on the Group.

The Group reached a settlement agreement with certain former shareholders of Jiangsu Quanyi in the second quarter of 2011, in respect of the acquisition of a 37.5% equity interest in Jiangsu Quanyi. Pursuant to the settlement agreement, the Group received a total of RMB50,000 in 2011, which was recognized as other operating income for the year ended December 31, 2011. In March 2012, the Group reached a settlement agreement with the selling shareholders and former directors of China Vax, in respect of the acquisition of 100% equity interest in China Vax. China Vax is a Cayman Islands investment holding company which then holds 15% equity interest in Jiangsu Quanyi. Pursuant to the settlement agreement, the Group agreed to pay US\$2,030 of the remaining consideration payable of US\$4,511 to the selling shareholders of China Vax. The reduction of the consideration payable of US\$2,481 (RMB15,650) representing the difference between US\$4,511 previously recognized as consideration payable (included in other current liabilities) and US\$2,030, the settlement amount was recognized as other operating income for the year ended December 31, 2012.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

During the year ended December 31, 2011, the Group underwent a restructuring of the vaccine reporting unit. Jiangsu Quanyi established a subsidiary, Jiangsu Simcere Vaxtec Bio-Pharmaceutical Co., Ltd. ( Jiangsu Vaxtec ), to take over the vaccine business from Jiangsu Quanyi. Jiangsu Vaxtec obtained the GMP certificate of influenza vaccine and commenced production in March 2013.

F-25

---



Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)**

The Group performed its annual goodwill impairment test as of December 31, 2012. Considering the Group's business strategy will focus on pharmaceutical business, the Group reassessed the commercialization of in-process R&D projects of vaccine business and revised the vaccine business plan. As a result, in 2012, a goodwill impairment loss of RMB25,316 (US\$4,063) was recognized in the vaccine reporting unit since the carrying amount of the reporting unit was greater than the fair value of the reporting unit (as determined using the expected present value of future cash flows) and the carrying amount of the reporting unit goodwill exceeded the implied fair value of that goodwill.

**8 Short-term borrowings**

Short-term borrowings consist of the following:

	<b>2011</b>	<b>December 31,</b>	<b>2012</b>
	<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
Unsecured government loan	8,000	18,000	2,889
Unsecured bank loans	710,000	620,009	99,518
Secured bank loans (note 3)	98,150	37,770	6,063
<b>Total</b>	<b>816,150</b>	<b>675,779</b>	<b>108,470</b>

Short-term bank loans bear fixed interest rates ranging from 6.10% to 7.93% per annum in 2011 and from 5.60% to 7.02% per annum in 2012, respectively. The weighted average effective interest rates on short-term borrowings outstanding as of December 31, 2011 and 2012 were 6.93% and 5.92% per annum, respectively.

As of December 31, 2011 and 2012, the Group had unutilized banking facilities of RMB266,000 and RMB280,000 (US\$44,943), respectively.

**9 Long-term borrowings**

Long-term borrowings consist of the following:

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

	2011 RMB	December 31, 2012 RMB	2012 US\$
Unsecured government loan with free interest		2,000	321
<b>Total long-term borrowings</b>		<b>2,000</b>	<b>321</b>

The unsecured government loan which is interest-free and due on February 9, 2015, does not contain any financial covenants or subjective acceleration clauses.

**10**                      **Income tax**

**Cayman Islands and British Virgin Islands**

Under the current laws of the Cayman Islands and British Virgins Islands, the Company and its subsidiaries incorporated in these jurisdictions are not subject to any income tax on their income or capital gains. In addition, upon receipt of payments of dividends by these companies, no Cayman Islands or British Virgins Islands withholding tax is imposed.

**United States**

Simcere of America Inc. ( Simcere America ) incorporated in the United States and is subject to United States federal and state income taxes. The applicable income tax rate is approximately 41%.

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

**People's Republic of China**

The Company's subsidiaries incorporated in the PRC file separate income tax returns.

Effective from January 1, 2008, under the Corporate Income Tax Law of the PRC (CIT law) which was passed by the National People's Congress on March 16, 2007, the PRC's statutory income tax rate is 25%.

The CIT law and its relevant regulations provide a five-year transition period for those enterprises which were established before March 16, 2007 and which were entitled to a preferential income tax rate of 15% under the then effective tax laws and regulations, and also grandfather certain tax holidays until they expire. The transitional tax rates are 22%, 24% and 25% for 2010, 2011 and 2012 onwards, respectively.

Further, under the CIT law and its relevant regulations, entities that qualify as Advanced and New Technology Enterprises (ANTEs) are entitled to a preferential income tax rate of 15%.

The Company's PRC subsidiaries are subject to income tax at 25%, except for the following:

- Hainan Simcere is subject to income tax at 11%, 15%, 15%, 15% and 25% for 2010, 2011, 2012, 2013 and 2014 onwards, respectively.
- Shandong Simcere is subject to income tax at 11%, 12%, 15%, 15% and 25% for 2010, 2011, 2012, 2013 and 2014 onwards, respectively.
- Nanjing Simcere Dongyuan Pharmaceutical Co., Ltd. (Nanjing Simcere) is subject to income tax at 12.5% for 2010, 15% from 2011 to 2014 and 25% from 2015 onwards.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

- Shanghai Simcere is subject to income tax at 22%, 24% and 25% for 2010, 2011 and 2012, respectively. The Group lost its controlling interest in Shanghai Simcere in July 2012.
  
- Jilin Boda and Wuhu Simcere Zhong Ren Pharmaceutical Co., Ltd. ( Simcere Zhong Ren) is subject to income tax rate at 15% from 2010 to 2013 and 25% from 2014 onwards.
  
- Jiangsu Quanyi is subject to income tax at 15% for 2010 and 25% from 2011 onwards.

The CIT law and its relevant regulations impose a withholding tax at 10%, unless reduced by a tax treaty or agreement, for dividends distributed by a PRC-resident enterprise to its non-PRC-resident corporate investor for earnings generated beginning on January 1, 2008. Undistributed earnings generated prior to January 1, 2008 are exempt from such withholding tax. As of December 31, 2012, the Group has not recognized a deferred tax liability of RMB109,623 (US\$17,596) for undistributed earnings of RMB1,096,232 (US\$175,957) generated by the PRC subsidiaries from 2008 to 2012 since the Group plans to indefinitely reinvest these earnings in the PRC.

The components of earnings (losses) before income taxes are as follows:

	2010 RMB	Year ended December 31,		2012 US\$
		2011 RMB	2012 RMB	
Cayman Islands	(34,040)	(33,323)	(25,009)	(4,014)
British Virgin Islands	(18,287)	(13,516)	4,756	763
United States		(4,947)	224	36
PRC	247,620	168,244	45	7
<b>Total</b>	<b>195,293</b>	<b>116,458</b>	<b>(19,984)</b>	<b>(3,208)</b>

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****(a) Income taxes**

Income tax expense (benefit) represents the following PRC and United states current income tax expense and deferred tax benefit:

	<b>Current RMB</b>	<b>Deferred RMB</b>	<b>Total RMB</b>	<b>Total US\$</b>
Year ended December 31, 2010				
PRC	38,362	(27,722)	10,640	
United States				
	38,362	(27,722)	10,640	
Year ended December 31, 2011				
PRC	30,837	(66,208)	(35,371)	
United States				
	30,837	(66,208)	(35,371)	
Year ended December 31, 2012				
PRC	35,906	(39,598)	(3,692)	(593)
United States		(1,889)	(1,889)	(303)
	35,906	(41,487)	(5,581)	(896)

**(b) Unrecognized tax benefits**

The following table summarizes the movement of unrecognized tax benefits:

	<b>2010 RMB</b>	<b>2011 RMB</b>	<b>2012 RMB</b>
Balance at January 1	19,928	19,928	19,928
Increase related to current year tax positions			
Balance at December 31	19,928	19,928	19,928
Balance at December 31 US\$			3,199

Unrecognized tax benefits of RMB19,928 as of each year end, if recognized, would affect the Group's effective income tax rate. For the years ended December 31, 2010, 2011 and 2012, the Group accrued interest of RMB1,032, RMB1,032 and RMB1,032 (US\$166), respectively, related to unrecognized tax benefits. As of December 31, 2010, 2011 and 2012, total recognized cumulative accrued interest related to

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

unrecognized tax benefits were RMB2,665 and RMB3,697 and RMB4,729 (US\$759), respectively. The Group did not recognize any penalty related to unrecognized tax benefits. The unrecognized tax benefits and related accrued cumulative interest were included in other liabilities in the consolidated balance sheets. Management believes that it is reasonably possible that approximately RMB5,733 (US\$920) of the unrecognized tax benefits as of December 31, 2012, may be recognized in the next twelve months as a result of a lapse of the statute of limitations.

According to the PRC Tax Administration and Collection Law, the statute of limitation is three years if the underpayment of taxes is due to computational errors made by the taxpayer or the withholding agent. The statute of limitation is extended to five years under special circumstances where the underpayment of taxes is more than RMB100 (US\$16). In the case of transfer pricing issues, the statute of limitation is ten years. There is no statute of limitation in the case of tax evasion. The income tax returns of the Company's PRC subsidiaries for the tax years beginning from 2002 are open to examination by the PRC state and local tax authorities.

Table of Contents

## Simcere Pharmaceutical Group and Subsidiaries

## Notes to Consolidated Financial Statements

(Amounts expressed in thousands, except share data)

(c) *Reconciliation of expected income tax to actual income tax expense*

The actual income tax expense (benefit) reported in the consolidated statements of income differs from the amounts computed by applying the PRC statutory income tax rate at 25% to earnings (losses) before income taxes as a result of the following:

	Note	2010 RMB	Year ended December 31,		2012 US\$
			2011 RMB	2012 RMB	
Computed expected income tax expense		48,823	29,114	(4,996)	(802)
Non-deductible expense					
Entertainment expense		2,373	3,746	5,710	917
Share based compensation cost		7,775	7,335	5,109	820
Reversal of deferred tax assets on accounts receivable		303		8,276	1,328
Penalty for quality issue of rabies vaccine		750			
Staff costs		554	262		
Impairment charges				6,329	1,016
R&D expense bonus deduction		(1,239)	(1,451)	(16,352)	(2,625)
Deemed income for free samples		7,437	4,713	2,320	372
Non-taxable income		(2,101)	(12,500)		
Tax rate differential and preferential rate		(24,200)	(19,982)	(18,641)	(2,992)
Tax rate differential for a non-PRC entity			(742)	36	6
Effect of tax holiday	(a)	(29,942)	(7,011)		
Non-PRC entities not subject to income tax		5,307	4,375	(46)	(7)
Change in valuation allowance		(6,855)	(42,078)	5,411	869
Interest for unrecognized tax benefits		1,032	1,032	1,032	166
Change in enacted tax rates or tax status			(2,686)	2,095	336
Intercompany intellectual property transfer		(594)	(730)	(1,555)	(250)
Others		1,217	1,232	(309)	(50)
<b>Actual income tax expense (benefit)</b>		<b>10,640</b>	<b>(35,371)</b>	<b>(5,581)</b>	<b>(896)</b>

Notes:

(a) The effect of tax holiday increased the Group's net income by RMB29,942 and RMB7,011 for the year ended December 31, 2010 and 2011. The Group did not enjoy any tax holiday for the year ended December 31, 2012. Consequently, the effect of the tax holiday increased the Group's basic and diluted earnings per share for such periods as follows:

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

	Year ended December 31,	
	2010	2011
	RMB	RMB
Increase in earnings per share:		
Basic	0.28	0.06
Diluted	0.27	0.06

F-29

---



Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****(d) *Deferred taxes***

The tax effects of the Group's temporary differences that give rise to significant portions of the deferred tax asset and liabilities are as follows:

	2011 RMB	December 31, 2012 RMB	2012 US\$
<b>Deferred tax assets:</b>			
Property, plant and equipment	9,086	10,405	1,670
Intangible assets	4,761	4,001	642
Accounts receivable	10,399	1,668	268
Inventories	3,014	1,532	246
Tax loss carryforwards	48,571	76,058	12,208
Accruals	53,462	53,902	8,652
Government grants	4,724	16,261	2,610
Total gross deferred tax assets	134,017	163,827	26,296
Valuation allowance	(2,340)	(7,751)	(1,244)
Net deferred tax assets	131,677	156,076	25,052
<b>Deferred tax liabilities</b>			
Intangible assets and land use right	(77,552)	(54,396)	(8,731)
Property, plant and equipment	(5,152)	(4,166)	(669)
Investment in an affiliated company		(7,143)	(1,146)
Government grant	(2,492)	(2,403)	(386)
	(85,196)	(68,108)	(10,932)
<b>Net deferred tax assets</b>	<b>46,481</b>	<b>87,968</b>	<b>14,120</b>
<b>Classification on consolidated balance sheets</b>			
Current:	79,620	111,706	17,930
Non-current (included in other non-current assets):	13,109	32,382	5,198
Deferred tax liabilities:			
Non-current portion	(46,248)	(56,120)	(9,008)

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible and tax loss carryforwards are utilized. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryforward periods), projected future taxable income, and tax planning strategies in making this assessment.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

As of December 31, 2012, the Group recognized net deferred tax assets of RMB87,968 (US\$14,120), among of which, certain subsidiaries recognized net deferred tax assets of RMB128,757 (US\$20,667) and certain subsidiaries recognized net deferred tax liabilities of RMB40,789 (US\$6,547), respectively. The subsidiaries in cumulative loss position recognized RMB127,265 (US\$20,427) of net deferred tax assets, mainly arising from the gross deferred tax assets of RMB73,775 (US\$11,842) and RMB46,484 (US\$7,461) relating to RMB292,269 (US\$46,912) in tax loss carryforwards and RMB185,935 (US\$29,845) in accrual. Among RMB292,269 (US\$46,912) of tax loss carryforwards, RMB287,546 (US\$46,154) were contributed by the Group's PRC subsidiaries, which will expire in varying amounts in 2015, 2016 and 2017, respectively, and the remaining RMB4,723 (US\$758) were contributed by the Group's United States subsidiary, which will expire in 2031. Realization is dependent on generating sufficient taxable income prior to expiration of the tax loss carryforwards. Although realization is not assured, management believes it is more likely than not that all of the net deferred tax asset will be realized. However, the amount of the deferred tax assets considered realizable could be reduced in the near term if estimates of future taxable income during the carryforward period are reduced.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)**

For the years ended December 31, 2011 and 2012, the change in valuation allowance was a decrease of RMB42,078 and an increase of RMB5,411 (US\$869), respectively. As of December 31, 2012, valuation allowances were provided against the deferred tax assets of Sichuan Zigong Yirong Industrial Co., Ltd. (Sichuan Simcere) and Jiangsu Quanyi, which was at cumulative loss positions. The increase in valuation allowance in 2012 was mainly due to the valuation allowance of RMB7,390 (US\$1,186) provided against the deferred tax assets of Sichuan Simcere and Jiangsu Quanyi, which was offset by the reversal of valuation allowance provided against the deferred tax assets of Simcere America by RMB1,979 (US\$318). Simcere America generated taxable income in 2012 and expects to generate further taxable income for it to utilize or recover its deferred tax assets.

Tax loss carryforwards of the Group's PRC subsidiaries amounted to RMB302,047 (US\$48,482) as of December 31, 2012, of which RMB238, RMB30,493, RMB115,056 and RMB156,260 will expire if unused by December 31, 2014, 2015, 2016 and 2017, respectively. Tax loss carryforwards of the Group's United States subsidiary amounted to US\$758 (RMB4,723) as of December 31, 2012, which will expire if unused by December 31, 2031.

**11 Other current liabilities**

Other current liabilities consist of the following:

	<b>2011</b>	<b>December 31,</b>	<b>2012</b>
	<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
Accrued marketing, traveling and conference expenses	120,545	104,950	16,846
Accrued construction costs and payable for acquisition of property, plant and equipment	69,046	39,829	6,393
VAT payable	48,304	46,629	7,484
Provision for rabies vaccine re-inoculation cost and penalty (note 7(e))	19,534	5,034	808
Government grants (note (a))	76,660	86,343	13,859
Payable for acquisitions (note (b))	41,810		
Security deposits from employees and agents (note (c))	22,835	17,923	2,877
Customer receipts in advance	4,909	5,666	909
Accrued research and development expenses	5,640	10,484	1,683
Accrued legal and professional fees	3,093	3,670	589
Other accrued liabilities (note (d))	58,476	57,940	9,300
Income taxes payable	11,039	15,729	2,525
Amount due to related party	8,788	10,025	1,609

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

<b>Total other current liabilities</b>	<b>490,679</b>	<b>404,222</b>	<b>64,882</b>
--	----------------	----------------	---------------

---

Notes:

(a) The amounts represent the deferred portion of conditional and refundable government grants received but not recognized since the conditions are subject to future events.

(b) As of December 31, 2011, the outstanding balance includes unpaid consideration payable of RMB28,422 for the acquisition of the additional 15% equity interest in Jiangsu Quanyi, unpaid consideration payable of RMB4,400 for the acquisition of the additional 39.19% equity interest in Jilin Boda and unpaid consideration payable of RMB8,988 for the acquisition of the redeemable non-controlling interest in Jilin Boda. These consideration payables were all settled as of December 31, 2012.

(c) The amounts represent refundable cash security deposits received from certain employees and from third party marketing agents.

(d) Other accrued liabilities relate to accruals for reimbursement payable to employees, other taxes and other miscellaneous expenses.

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

**12 Statutory reserves**

Under PRC rules and regulations, the Company's PRC operating subsidiaries are required to provide for certain statutory reserves as follows:

*Statutory surplus reserve*

According to the respective Articles of Association, the Company's PRC operating subsidiaries are required to transfer 10% of their net profit, as determined in accordance with PRC GAAP, to a statutory surplus reserve until the reserve balance reaches 50% of the registered capital of the respective companies. The transfer to this reserve must be made before distribution of dividends to shareholders can be made.

The statutory surplus reserve can be used to make good previous years' losses, if any, and may be converted into share capital by the issue of new shares to shareholders in proportion to their existing shareholdings or by increasing the par value of the shares currently held by the shareholders, provided that the balance after such issue is not less than 25% of the registered capital.

For the years ended December 31, 2010, 2011 and 2012, the Company's subsidiaries made appropriation to these statutory reserve funds of RMB31,048 and RMB16,834 and RMB14,928 (US\$2,396), respectively. The accumulated balance of the statutory reserve funds maintained at the Company's PRC operating subsidiaries as of December 31, 2011 and 2012 were RMB213,622 and RMB228,550 (US\$36,685), respectively.

**13 Pension and other postretirement benefits**

Pursuant to the relevant PRC regulations, the Group is required to make contributions for each employee at a rate of approximately 20% on a standard salary base as determined by the local Social Security Bureau to a defined contribution retirement scheme organized by the local Social Security Bureau in respect of the retirement benefits for the Group's employees in the PRC. Contributions of RMB15,644, RMB22,665 and RMB24,163 (US\$3,878) for the years ended December 31, 2010, 2011 and 2012, respectively, were charged to expense. The Group has no other obligation to make payments in respect of retirement benefits of the employees.

**14**                      **Commitments and contingencies**

(a)                      *Operating lease commitments*

The Group leases certain offices under various operating lease arrangements. The rental expenses under the operating leases was RMB1,493, RMB6,008 and RMB7,623 (US\$1,224) for the years ended December 31, 2010, 2011 and 2012, respectively. In the normal course of business, leases that expire are renewed or replaced by leases on other properties. As of December 31, 2012, the Group's future minimum rental payment under non-cancellable operating leases is as follows:

	<b>December 31,</b>
	<b>2012</b>
	<b>RMB</b>
2013	1,792
2014	367
2015	234
2016	3
2017	3
Thereafter	12
<b>Total</b>	<b>2,411</b>

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

(b) ***Commitments***

As of December 31, 2012, the Group's capital commitments for purchase of machinery and equipment are RMB863 (US\$139).

As of December 31 2012, the Group's commitments for research and development projects is RMB22,776 (US\$3,656).

(c) ***Depository receipt facility***

During the years ended December 31, 2010, 2011 and 2012, the Company received an incentive payment of RMB1,056, RMB1,025 and RMB1,006 (US\$160) respectively, which is recognized as other income in the consolidated statements of comprehensive income, from a bank in order to provide that bank with the exclusive right to manage the Company's American Depository Receipt (ADR) program. Under the terms of the depository receipt facility with the bank, in the event the Company terminates the ADR program or the number of ADRs outstanding declines by more than 50%, the Company must reimburse the bank up to the amount that equates to total incentive payments received by the Company of RMB24,635 (US\$3,954) as of December 31, 2012.

(d) ***Sales of bills receivable commitments***

As of December 31, 2011 and 2012, outstanding bills receivable discounted with third party financial institutions and endorsed to third party suppliers for which the Group has a recourse obligation amounted to RMB40,560 and RMB155,046 (US\$24,887), respectively. The Group has not historically experienced credit losses with respect to bills receivable sold or endorsed with recourse. No recourse liability was recognized as of December 31, 2011 and 2012 as the estimated fair value of the recourse obligation was immaterial.

**15 Earnings per share**

The following table sets forth the computation of basic and diluted earnings per share:

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

	2010	Year ended December 31,		2012
	RMB	2011 RMB	2012 RMB	2012 US\$
<b><i>Numerator for basic and diluted earnings per share:</i></b>				
Net income attributable to Simcere Pharmaceutical Group	172,411	178,389	56,957	9,142
<b><i>Denominator:</i></b>				
Basic weighted average number of ordinary shares outstanding	108,321,562	109,738,705	106,996,531	106,996,531
Effect of dilutive options and non-vested shares	3,036,234	786,552	374,299	374,299
Diluted weighted average number of ordinary shares outstanding	111,357,796	110,525,257	107,370,830	107,370,830
Basic earnings per share	1.59	1.63	0.53	0.09
Diluted earnings per share	1.55	1.61	0.53	0.09

The computation of diluted earnings per share for the years ended December 31, 2010, 2011 and 2012 did not assume exercise of 978,000, 857,700 and 729,700 share options, respectively, because the exercise prices of the share options were greater than or equal to the average price of the ordinary shares during the year, and therefore their inclusion would have been anti-dilutive.



Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****16 Revenue**

Revenue by product category is summarized as follows:

	Year ended December 31,			
	2010 RMB	2011 RMB	2012 RMB	2012 US\$
Cardiovascular and Cerebrovascular	800,979	779,846	755,164	121,212
Antibiotics	435,797	313,464	356,013	57,144
Anti-cancer	417,199	522,373	556,150	89,268
Anti-inflammatory drugs	219,550	185,441	202,767	32,546
Vaccine	62,947	222	241	39
Other medicines	204,626	239,201	212,631	34,130
<b>Total revenue</b>	<b>2,141,098</b>	<b>2,040,547</b>	<b>2,082,966</b>	<b>334,339</b>

**17 Share-based compensation**

On November 13, 2006 and July 31, 2008, the shareholders of the Company adopted the 2006 Share Incentive Plan (the "2006 Share Incentive Plan") and the 2008 Share Incentive Plan (the "2008 Share Incentive Plan") which provides for the granting of options, share appreciation rights, and other share-based awards such as non-vested shares to the directors and employees of the Group. The board of directors and shareholders of the Company has authorized the issuance of up to 12,000,000 and 6,250,000 ordinary shares upon exercise of awards granted under the 2006 Share Incentive Plan and the 2008 Share Incentive Plan, respectively.

*Share options*

The following is a summary of share options granted during the year ended December 31, 2010. No options were granted in 2011 or 2012 under the 2006 Share Incentive Plan.

	Year ended December 31,		
	2010	2011	2012
Total number of share options granted	978,000		
Weighted average exercise price per share (US\$/share)	US\$ 4.545		

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Weighted average vesting period (in years)	3.00
Weighted average contractual life (in years)	6.00

Management has determined, based on the Black-Scholes-Merton option-pricing model, that the weighted average grant-date fair value per option was approximately US\$2.35 (RMB15.51 translated at the exchange rate on December 31, 2010) or an aggregate of RMB15,169 for the years ended December 31, 2010.

The weight average assumptions used in determining the fair value of the share options granted during the year ended December 31, 2010 are provided as follows:

	Year ended December 31,		
	2010	2011	2012
Valuation assumptions			
Expected term (in years)	4.5		
Expected volatility	64.73%		
Expected dividend	0%		
Risk-free rate	0.75%-1.41%		

The expected term is based on the simplified method by averaging the vesting term and contractual term. Since the share options granted prior to year 2009 were exchanged to non-vested shares in May 2009, the Group is unable to rely on historical exercise data to estimate the expected term of the share options granted in 2010.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)**

The expected volatility of share options is estimated based on the Company's historical share price using the expected life of the grant. The risk free rate is based on the yield of US Treasury bond rate.

Since the Company's share options have certain characteristics that are significantly different from traded options, and changes in the subjective assumptions can materially affect the estimated value, the existing valuation model may not provide an accurate measure of the fair value of the Company's employee stock options. Although the fair value of share options is determined using the Black-Scholes option pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

A summary of stock option activity is as follows:

	Number of options	Weighted average exercise price US\$	Weighted average remaining contractual term Years	Aggregate intrinsic value US\$
Balance as of December 31, 2009				
Granted	978,000	4.55		
Balance as of December 31, 2010	978,000	4.55		
Exercised	(800)	4.55		
Forfeited	(119,500)	4.55		
Balance as of December 31, 2011	857,700	4.55		
Forfeited	(128,000)	4.55		
Balance as of December 31, 2012	729,700	4.55	2.67	(383)
Vested and expected to vest as of December 31, 2012	654,543	4.55	2.67	(344)
Exercisable as of December 31, 2012	296,200	4.55	2.67	(156)

The total fair value of share options vested during the years ended December 31, 2011 and 2012 was RMB4,899 and RMB3,596 (US\$577), respectively. No share option was vested during the year ended December 31, 2010. The total intrinsic values of options exercised during the years ended December 31, 2011 was RMB2 (US\$0.3). No share options were exercised during the year ended December 31, 2010 and 2012.

As of December 31, 2012, there was RMB5,734 (US\$920) of total unrecognized compensation cost related to share options that is expected to be recognized on a straight line basis over a weighted average period of 2.67 years.

*Non-vested shares*

On April 15, 2009, the Compensation Committee of the Company approved a share option exchange program that offered the directors, employees and consultants the right to exchange vested and unvested outstanding share options to purchase ordinary shares of the Company under the 2006 Share Incentive Plan for the Company's vested and non-vested shares. Non-vested shares are subject to restrictions on their sale or transfer by the holder. Under the share option exchange program, the non-vested shares vest on the same term as the original grants made under 2006 Share Incentive Plan. Upon exercise of non-vested shares, the holders are required to pay the par value at US\$0.01 (RMB0.06) per share.

A total of 154 directors and employees accepted the offer and tendered an aggregate of 9,802,400 options in exchange for 1,833,990 vested shares and 2,916,028 non-vested shares on May 7, 2009, the modification date. The exchange ratio was determined based on the fair value of the vested and non-vested shares divided by the fair value of the share options surrendered. The exchange of the share option awards for the vested and non-vested shares was accounted for as a modification of awards which involves a cancellation of the original award and an issuance of a new award. The effect of this award modification on share-based compensation expense over the remaining requisite service period was not significant.

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)**

During the years ended December 31, 2010, 2011 and 2012, 870,000, 364,000 and 4,140,000 non-vested shares were granted, respectively, under the 2006 Share Incentive Plan with terms ranging from 3 to 5 years. During the years ended December 31, 2012, 2,000,000 non-vested shares were granted under the 2008 Share Incentive Plan with a term of 5 years.

During the years ended December 31, 2010, 2011 and 2012, 518,322, 243,870 and 213,388 non-vested shares were exercised, respectively.

A summary of non-vested shares activity is as follows:

	Number of non-vested shares	Weighted average grant- date fair value US\$
Balance as of January 1, 2010	2,056,830	3.44
Granted	870,000	4.48
Vested	(993,068)	3.47
Forfeited	(13,336)	3.38
Balance as of December 31, 2010	1,920,426	3.90
Granted	364,000	5.96
Vested	(1,035,452)	3.64
Forfeited	(248,548)	3.78
Balance as of December 31, 2011	1,000,426	4.94
Granted	6,140,000	3.84
Vested	(378,346)	4.83
Forfeited	(96,988)	4.53
Balance as of December 31, 2012	6,665,092	3.94
Vested but not exercised as of December 31, 2012	3,683,152	3.59

The total fair value of non-vested shares vested during the years ended December 31, 2010, 2011 and 2012 was RMB33,759, RMB30,727 and RMB10,296 (US\$1,653).

As of December 31, 2012, there was RMB147,385 (US\$23,657) of total unrecognized compensation cost related to non-vested shares that is expected to be recognized on a straight-line basis over a weighted average period of 4.54 years.

Share-based compensation cost is included in the following captions:

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

	2010	Year ended December 31,		2012
	RMB	2011	2012	US\$
		RMB	RMB	
Research and development expenses	3,599	3,960	2,575	413
Sales, marketing and distribution expenses	3,810	5,414	4,341	697
General and administrative expenses	23,690	19,967	13,521	2,170
<b>Total share-based compensation</b>	<b>31,099</b>	<b>29,341</b>	<b>20,437</b>	<b>3,280</b>

F-36

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)****18 Share repurchases**

On November 4, 2008, the board of directors of the Company approved a share repurchase program that allows the Company to purchase up to US\$50,000 of its issued and outstanding ADSs. On November 18, 2009, the board of directors of the Company approved a new share repurchase program that allows the Company to purchase up to US\$50,000 of its issued and outstanding ADSs. On November 11, 2011, the board of directors of the Company approved a share repurchase program that allows the Company to purchase up to US\$30,000 of its issued and outstanding ADSs.

In 2010, the Company repurchased and cancelled an aggregate of 2.1 million ADSs at an average per share price of US\$4.37 for a total cost of US\$18,831, including US\$178 handling charges. In 2011, the Company repurchased an aggregate of 0.6 million ADSs at an average per share price of US\$3.86 for a total cost of US\$5,048, including US\$52 handling charges, and cancelled these ADSs in 2012. In 2012, the Company repurchased an aggregate of 2.3 million ADSs at an average per share price of US\$4.21 (RMB26.23) for a total cost of US\$19,291 (RMB121,923), including US\$182 (RMB1,134) handling charges. 2.0 million ADSs was cancelled in 2012 and the remaining 0.3 million ADSs was cancelled in 2013.

**19 Related party transactions**

For the years presented, the principal related party transactions and amounts due from and due to related parties are summarized as follows:

	2010 RMB	Year ended December 31		2012 US\$
		2011 RMB	2012 RMB	
Purchase of packaging and raw materials from related parties (note (a))	23	454	494	79
Sales of products to related parties (note (b))	6,158	8,678	34,852	5,594
Interest income from loan to a related party (note (c))	1,274	1,506	1,130	181
Repayment from a related party (note (c))		1,325	8,303	1,333
Interest income from advances to an affiliated company (note (d))	1,485	1,827	828	133
Advance to an affiliated company (note (d))	12,600			
Repayment from an affiliated Company (note (d))		19,500		
Interest expense from loans to related parties (note (e))			270	43
Borrowing of loans from related parties (note (e))			15,000	2,408
Repayment of loans to related parties (note (e))			15,000	2,408
			5,020	806

Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

Advance to a related party for research and development services (note (c))

	<b>2011 RMB</b>	<b>December 31, 2012 RMB</b>	<b>2012 US\$</b>
Due from related parties:			
Current portion	9,661	32,912	5,283
Non-current portion	16,000	6,000	963
Due from related parties (note (c) and (d))	25,661	38,912	6,246
Advances to an affiliated company (note (d))	16,160		
Due to related parties (note (f) and note 11)	8,788	10,025	1,609

F-37



Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

---

Notes:

(a) The Group purchased packaging and raw materials from a non-controlling shareholder of a subsidiary and a company in which a major shareholder of the Company has an equity interest.

(b) The Group sold pharmaceutical products to the companies in which a major shareholder of the Company has an equity interest and the affiliated company, Simcere MSD.

(c) The Group lent a secured loan with principal of RMB21,600 to a non-controlling shareholder of a subsidiary. The secured loan bears a floating interest rate equal to RMB benchmark lending rates of financial institutions multiplied by 120% and is secured by non-controlling shareholder's entire equity interest in the subsidiary. As agreed in the renewed loan contract on July 1, 2011, the loan would be repaid in several installments, RMB5,600, RMB10,000 and RMB6,000 being repaid before June 30, 2012, 2013 and 2014, respectively. As of December 31, 2011, RMB5,600 of principal and RMB2,155 of accrued interest were classified as current portion of amount due from related parties and the remaining RMB16,000 were classified as non-current portion of amount due from related parties. As of December 31, 2012, the unpaid principal of RMB10,000 (US\$1,605) due on June 30, 2013 and accrued interest of RMB582 (US\$93), were classified as current portion of amount due from related parties and the unpaid principal of RMB6,000 (US\$963) due on June 30, 2014 was classified as non-current portion of amount due from related parties.

The current portion of amounts due from related parties related to transactions described in note (b) above as of December 31, 2011 and 2012 were RMB774 and RMB322 (US\$52), respectively. These amounts were interest-free, unsecured and repayable on demand. The current portion as of December 31, 2011 and 2012 also included advance payment of RMB1,132 and RMB5,020 (US\$806) to related parties and the amount is interest-free, unsecured and repayable on demand.

(d) The Group lent unsecured loans to the affiliated company, Shanghai Celgen. As of December 31, 2011, the amount included the loan principal of RMB12,600 and the accrued interest of RMB3,560. As described in note 1(c), the investment in Shanghai Celgen was classified as assets held for sale as of December 31, 2012. As agreed in the renewed loan contract on October 28, 2012, the loan would be repaid on April 30, 2013. Accordingly, the related loan principal of RMB12,600 (US\$2,023) and the accrued interest of RMB4,388 (US\$704) were classified as current portion of amount due from related parties as of December 31, 2012.

(e) The Group borrowed loans of RMB15,000 (US\$2,408) from related parties for daily operation in 2012 and repaid it in 2012. The related interest was RMB270 (US\$43).

(f) The amount as of December 31, 2011 represented the unpaid dividend declared by Simcere Zhong Ren in 2011 attributable to the non-controlling shareholder. The amount as of December 31, 2012 represented the sales commission payable to Simcere MSD of RMB9,892 (US\$1,588) and the purchased material payable to a non-controlling shareholder of Simcere Zhong Ren of RMB133 (US\$21).

**20 Collaborative arrangements**

On December 12, 2008, the Group entered into an agreement to collaborate on the co-development and production of humanized antibody therapeutics for tumors with Epitomics, Inc., a provider of humanized rabbit monoclonal antibodies for therapeutic use. Under the agreement, the Group and Epitomics, Inc. will collaborate on pre-clinical and clinical trials, product manufacturing, and product distribution in the international markets. The Group will have the exclusive production and distribution rights in China. The Group agreed to pay a total funding of up to US\$5,000 (RMB31,150) of which US\$1,000 was paid in 2009 to acquire the license rights of in-process R&D materials in China. US\$1,000 (RMB6,230) was paid in 2012 upon receipt of clinical trial approval from the China Food and Drug Administration of the PRC. The remaining US\$3,000 (RMB18,690) will be paid at various dates upon the achievement of certain milestones as set forth under the agreement.

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

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

Table of Contents

**Simcere Pharmaceutical Group and Subsidiaries**

**Notes to Consolidated Financial Statements**

**(Amounts expressed in thousands, except share data)**

As at December 31, 2012, the subject pharmaceutical was still undergoing development and has not reached the stage of commercialization in China or outside of China, and therefore no revenue or profits have been generated from this project. There was also no significant related development costs incurred outside of China during 2012.

**21 Fair value measurements**

Management used the following methods and assumptions to estimate the fair value of financial instruments as of December 31, 2011 and 2012:

- Short-term financial instruments (pledged bank deposits, trade accounts receivable, bills receivable and other receivables, amounts due from related parties, short-term borrowings, trade accounts payable, amounts due to related parties, and other payables and accrued liabilities) their carrying amounts approximated their respective fair values because of the short maturity period.
- Long-term loans and long-term loan receivable their fair values are based on the amount of future cash flows associated with these instruments discounted at the borrowing and lending rates currently available for similar instruments of comparable terms. Their carrying values of the long-term loans and long-term receivable approximated their fair values as all these instruments carry variable interest rates which approximated rates currently offered by the Group's financial institutions for similar instruments of comparable maturities.
- The fair value of investment in an affiliate company, goodwill and IPR&D is determined by estimating the expected present value of future cash flows without reference to observable market transactions.

**22 Simcere Pharmaceutical Group (parent company)**

Relevant PRC statutory laws and regulation permit payments of dividends by the Company's subsidiaries in the PRC only out of their retained earnings, if any, as determined in accordance with the PRC accounting standards and regulations.

As of December 31, 2011 and 2012, RMB213,622 and RMB228,550 (US\$36,685) were appropriated from retained earnings and set aside for the statutory reserve by the Company's PRC subsidiaries, respectively.

## Edgar Filing: Simcere Pharmaceutical Group - Form 20-F

As a result of these PRC laws and regulations, the Company's subsidiaries in the PRC are restricted in its ability to transfer a portion of its net assets to either in the form of dividends, loans or advances, which consisted of registered capital and statutory reserves that amounted to RMB1,117,665 and RMB1,269,613 (US\$203,787) as of December 31, 2011 and 2012, respectively.

The following presents condensed unconsolidated financial information of the parent company only.

### *Condensed Balance Sheets*

	2011 RMB	December 31, 2012 RMB	2012 US\$
Cash	13,487	11,667	1,873
Other current assets	1,022	1,499	240
Due from subsidiaries	555,885	432,643	69,444
Investment in subsidiaries	1,509,755	1,592,867	255,673
Total assets	2,080,149	2,038,676	327,230
Due to subsidiaries	23,522	23,524	3,776
Other current liability	446	3,026	486
Total shareholders' equity	2,056,181	2,012,126	322,968
Total liabilities and equity	2,080,149	2,038,676	327,230

Table of Contents**Simcere Pharmaceutical Group and Subsidiaries****Notes to Consolidated Financial Statements****(Amounts expressed in thousands, except share data)***Condensed Statements of operations*

	<b>2010</b>	<b>Year ended December 31,</b>		<b>2012</b>
	<b>RMB</b>	<b>2011</b>	<b>2012</b>	<b>2012</b>
		<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
Equity in earnings of subsidiaries	206,451	211,712	81,966	13,156
Operating expense	(34,797)	(33,737)	(25,963)	(4,167)
Interest income	1	1	2	
Foreign currency exchange loss, net	(327)	(612)	(54)	(9)
Other income	1,083	1,025	1,006	162
Earnings before income taxes	172,411	178,389	56,957	9,142
Income taxes				
<b>Net income</b>	<b>172,411</b>	<b>178,389</b>	<b>56,957</b>	<b>9,142</b>

*Condensed Statements of Cash Flows*

	<b>2010</b>	<b>Year ended December 31,</b>		<b>2012</b>
	<b>RMB</b>	<b>2011</b>	<b>2012</b>	<b>2012</b>
		<b>RMB</b>	<b>RMB</b>	<b>US\$</b>
Net cash used in operating activities	(786)	(3,668)	(2,370)	(380)
Net cash (used in) provided by financing activities	(4,582)	4,407	575	92
Effect of exchange rate changes on cash and cash equivalent	(486)	(1,315)	(25)	(4)
<b>Net decrease in cash</b>	<b>(5,854)</b>	<b>(576)</b>	<b>(1,820)</b>	<b>(292)</b>
<b>Cash at the beginning of the year</b>	<b>19,917</b>	<b>14,063</b>	<b>13,487</b>	<b>2,165</b>
<b>Cash at the end of the year</b>	<b>14,063</b>	<b>13,487</b>	<b>11,667</b>	<b>1,873</b>