#### 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 П **EXCHANGE ACT OF 1934** ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE |X|**ACT OF 1934** For the fiscal year ended December 31, 2017 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES **EXCHANGE ACT OF 1934** For the transition period from to 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 Commission file number 001-37710 HUTCHISON CHINA MEDITECH LIMITED (Exact name of Registrant as specified in its charter) (Translation of Registrant's name into English) Cavman Islands (Jurisdiction of incorporation or organization) 22/F Hutchison House 10 Harcourt Road Hong Kong +852 2121 8200 (Address of principal executive offices) Christian Hogg Chief Executive Officer
Hutchison China MediTech Limited Room 2108, 21/F, Hutchison House 10 Harcourt Road Hong Kong Telephone: +852 2121 8200 Facsimile: +852 2121 8281 (Name, telephone, email 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 one-half of one Nasdaq Global Select Market ordinary share, par value \$1.00 per share Securities registered or to be registered pursuant to Section 12(g) of the Act: None (Title of Class) Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None (Title of Class) Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the Annual Report: 66,447,037 ordinary shares were issued and outstanding as of December 31, 2017. Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. 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. Note—checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those sections. 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. 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). Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act. Large accelerated filer  $\boxtimes$ Accelerated filer Non-accelerated filer □ Emerging growth company  $\square$ If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards<sup>†</sup> provided pursuant to Section 13(a) of the Exchange †The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012. 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 Other by the International Accounting Standards Board  $\square$ 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).  $\square$ 

☐ Yes 🖂 No

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#### Introduction

This annual report on Form 20-F contains our audited consolidated statements of operations data for the years ended December 31, 2017, 2016 and 2015 and our audited consolidated balance sheet data as of December 31, 2017 and 2016. Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. Our historical consolidated financial statements which we made publicly available prior to our listing on the Nasdaq Global Select Market in connection with the listing of our ordinary shares on the AIM market were prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.

This annual report also includes audited consolidated income statement data for the years ended December 31, 2017, 2016 and 2015 and the audited consolidated statements of financial position data as of December 31, 2017 and 2016 for each of our three non-consolidated joint ventures, Shanghai Hutchison Pharmaceuticals, Hutchison Baiyunshan and Nutrition Science Partners, which are accounted for using the equity accounting method. These consolidated financial statements have been prepared in accordance with IFRS as issued by the IASB.

Unless the context requires otherwise, references herein to the "company," "Chi-Med," "we," "us" and "our" refer to Hutchison China MediTech Limited and its consolidated subsidiaries and joint ventures.

### Conventions Used in this Annual Report

Unless otherwise indicated, references in this annual report to:

- "ADRs" are to the American depositary receipts, which evidence our ADSs;
- "ADSs" are to our American depositary shares, each of which represents one-half of one ordinary share;
- "China" or "PRC" are to the People's Republic of China, excluding, for the purposes of this annual report only, Taiwan and the special administrative regions of Hong Kong and Macau;
- "CK Hutchison" are to CK Hutchison Holdings Limited, a company incorporated in the Cayman Islands and listed on The Stock Exchange of Hong Kong Limited, or the Hong Kong Stock Exchange, and the ultimate parent company of our majority shareholder, Hutchison Healthcare Holdings Limited;
- "Guangzhou Baiyunshan" are to Guangzhou Baiyunshan Pharmaceutical Holdings Company Limited, a leading China-based pharmaceutical company listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange;
- "Hain Celestial" are to The Hain Celestial Group, Inc., a Nasdaq-listed, natural and organic food and personal care products company;
- "HK\$" or "HK dollar" are to the legal currency of the Hong Kong Special Administrative Region;
- "Hutchison Baiyunshan" are to Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited, our non-consolidated joint venture with Guangzhou Baiyunshan in which we have a 50% interest through a holding company in which we have a 80% interest;
- "Hutchison Consumer Products" are to Hutchison Consumer Products Limited, our wholly owned subsidiary;
- "Hutchison Hain Organic" are to Hutchison Hain Organic Holdings Limited, our joint venture with Hain Celestial in which we have a 50% interest;
- "Hutchison Healthcare" are to Hutchison Healthcare Limited, our wholly owned subsidiary;

- "Hutchison MediPharma" are to Hutchison MediPharma Limited, our subsidiary through which we operate our Innovation Platform in which we have a 99.8% interest;
- "Hutchison MediPharma Holdings" are to Hutchison MediPharma Holdings Limited, our subsidiary in which we have a 99.8% interest and which is the indirect holding company of Hutchison MediPharma;
- "Hutchison Sinopharm" are to Hutchison Whampoa Sinopharm Pharmaceuticals (Shanghai) Company Limited, our joint venture with Sinopharm in which we have a 51% interest;
- "Nutrition Science Partners" are to Nutrition Science Partners Limited, our non-consolidated joint venture with Nestlé Health Science S.A. in which we have a 50% interest;
- "ordinary shares" or "shares" are to our ordinary shares, par value \$1.00 per share;
- "RMB" or "renminbi" are to the legal currency of the PRC;
- "Shanghai Hutchison Pharmaceuticals" are to Shanghai Hutchison Pharmaceuticals Limited, our non-consolidated joint venture with Shanghai Pharmaceuticals in which we have a 50% interest;
- "Shanghai Pharmaceuticals" are to Shanghai Pharmaceuticals Holding Co., Ltd., a leading pharmaceutical company in China listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange;
- "Sinopharm" are to Sinopharm Group Co. Ltd., a leading distributor of pharmaceutical and healthcare products and a leading supply chain service provider in China listed on the Hong Kong Stock Exchange;
- "United States" or "U.S." are to the United States of America;
- "\$" or "U.S. dollars" are to the legal currency of the United States; and
- "£" or "pound sterling" are to the legal currency of the United Kingdom.

Our reporting currency is the U.S. dollar. In addition, this annual report also contains translations of certain foreign currency amounts into U.S. dollars for the convenience of the reader. Unless otherwise stated, all translations of pound sterling into U.S. dollar were made at £1.00 to \$1.34 and all translations of HK dollars into U.S. dollars were made at HK\$7.80 to \$1.00, which are the exchange rates used in our audited consolidated financial statements as of and for the year ended December 31, 2017. We make no representation that the pound sterling, HK dollar or U.S. dollar amounts referred to in this annual report could have been or could be converted into U.S. dollars, pounds sterling or HK dollars, as the case may be, at any particular rate or at all.

#### **Trademarks and Service Marks**

We own or have been licensed rights to trademarks, service marks and trade names for use in connection with the operation of our business, including, but not limited to, our trademark Chi-Med. All other trademarks, service marks or trade names appearing in this annual report that are not identified as marks owned by us are the property of their respective owners.

Solely for convenience, the trademarks, service marks and trade names referred to in this annual report are listed without the ®, (TM) and (sm) symbols, but we will assert, to the fullest extent under applicable law, our applicable rights in these trademarks, service marks and trade names.

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other 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. The words "anticipate," "assume," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "intend," "may," "might," "objective," "plan," "potential," "predict," "project," "positioned," "seek," "should," "target," "will," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions, are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors. These forward-looking statements include statements regarding:

- the initiation, timing, progress and results of our or our collaboration partners' pre-clinical and clinical studies, and our research and development programs;
- our or our collaboration partners' ability to advance our drug candidates into, and/or successfully complete, clinical studies;
- the timing or regulatory filings and the likelihood of favorable regulatory outcomes and approvals;
- regulatory developments in China, the United States and other countries;
- the adaptation of our Commercial Platform to market and sell our drug candidates and the commercialization of our drug candidates, if approved;
- the pricing and reimbursement of our and our joint ventures' products and our drug candidates, if approved;
- our ability to contract on commercially reasonable terms with contract research organizations, or CROs, third-party suppliers and manufacturers;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our or our joint ventures' products and our drug candidates;
- the ability of third parties with whom we contract to successfully conduct, supervise and monitor clinical studies for our drug candidates;
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- our ability to obtain additional funding for our operations;
- the potential benefits of our collaborations and our ability to enter into future collaboration arrangements;
- the ability and willingness of our collaborators to actively pursue development activities under our collaboration agreements;
- our or our joint venture Nutrition Science Partners' receipt of milestone or royalty payments pursuant to our strategic alliances with AstraZeneca AB (publ), or AstraZeneca, Lilly (Shanghai) Management Company Limited (formerly known as Eli Lilly Trading (Shanghai) Company Limited), or Eli Lilly, and Nestlé Health Science S.A., or Nestlé Health Science, as applicable;
- the rate and degree of market acceptance of our drug candidates;
- our financial performance;
- our ability to attract and retain key scientific and management personnel;

- our relationship with our joint venture and collaboration partners;
- developments relating to our competitors and our industry, including competing drug products; and
- changes in our tax status or the tax laws in the jurisdictions that we operate.

Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. As a result, any or all of our forward-looking statements in this annual report may turn out to be inaccurate. We have included important factors in the cautionary statements included in this annual report on Form 20-F, particularly in the section of this annual report on Form 20-F titled "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Moreover, we operate in a highly competitive and rapidly changing environment in which new risks often emerge. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make.

You should read this annual report and the documents that we reference herein and have filed as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained herein are made as of the date of this annual report, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

In addition, this annual report contains statistical data and estimates that we have obtained from industry publications and reports generated by third-party market research firms. Although we believe that the publications, reports and surveys are reliable, we have not independently verified the data and cannot guarantee the accuracy or completeness of such data. You are cautioned not to give undue weight to this data. Such data involves risks and uncertainties and are subject to change based on various factors, including those discussed above.

#### 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.

### **Our Selected Financial Data**

The following tables set forth our selected consolidated financial data. We have derived the selected consolidated statements of operations data for the years ended December 31, 2017, 2016 and 2015 and the selected consolidated balance sheet data as of December 31, 2017 and 2016 from our audited consolidated financial statements, which were prepared in accordance with U.S. GAAP and are included in this annual report. You should read this data together with such consolidated financial statements and the related notes and Item 5 "Operating and Financial Review and Prospects." Our historical results are not necessarily indicative of the results to be expected for any future periods. All of our operations are continuing operations and we have not proposed or paid dividends in any of the periods presented.

The following selected consolidated financial data for the years ended December 31, 2014 and 2013 and as of December 31, 2015 and 2014 have been derived from our audited consolidated financial statements for those years, which were prepared in accordance with U.S. GAAP and are not included in this annual report.

Vear	Ended	December	31

	Year Ended December 31,									
		2017		2016		2015		2014		2013
			(in	thousands, e	exce	pt share and	d per share data)			
Consolidated statements of operations data:										
Revenues										
Sales—third parties	\$	196,720	\$	171,058	\$	118,113	\$	59,162	\$	8,667
Sales—related parties		8,486		9,794		8,074		7,823		7,803
Revenue from license and collaboration agreements—		26.215		26.444		44.060		10.006		14546
third parties Revenue from research and development services—third		26,315		26,444		44,060		12,336		14,546
parties				355		2,573		3,696		1,919
Revenue from research and development services—				333		2,373		3,070		1,515
related parties		9,682		8,429		5,383		4,312		3,612
Total revenues	_	241,203	_	216,080	_	178,203	_	87,329	_	36,547
Operating expenses	-	211,200	-	210,000	-	170,200	-	07,025	-	00,017
Costs of sales—third parties		(169,764)		(149,132)		(104,859)		(53,477)		(5,380)
Costs of sales—related parties		(6,056)		(7,196)		(5,918)		(5,372)		(5,814)
Research and development expenses		(75,523)		(66,871)		(47,368)		(29,914)		(22,731)
Selling expenses		(19,322)		(17,998)		(10,209)		(4,112)		(3,452)
Administrative expenses		(23,955)		(21,580)		(19,620)		(12,713)		(12,366)
Total operating expenses	_	(294,620)	_	(262,777)		(187,974)		(105,588)		(49,743)
Loss from operations	_	(53,417)		(46,697)		(9,771)	-	(18,259)	-	(13,196)
Other income/(expense)		(33,417)		(40,057)		(9,771)		(10,239)		(13,170)
Interest income		1,220		502		451		559		451
Gain on disposal of a business				_		_		_		30,000
Other income		808		609		386		20		1,221
Interest expense		(1,455)		(1,631)		(1,404)		(1,516)		(1,485)
Other expense		(692)		(139)		(202)		(761)		(69)
Total other income/(expense)		(119)		(659)		(769)		(1,698)		30,118
(Loss)/income before income taxes and equity in		` ,		` ′		` ′		. , ,		,
earnings of equity investees		(53,536)		(47,356)		(10,540)		(19,957)		16,922
Income tax expense		(3,080)		(4,331)		(1,605)		(1,343)		(1,050)
Equity in earnings of equity investees, net of tax		33,653		66,244		22,572		15,180		11,031
Net (loss)/income from continuing operations		(22,963)		14,557		10,427	Т	(6,120)		26,903
Income/(loss) from discontinued operations, net of tax						´ —	2,034			(1,978)
Net (loss)/income	_	(22,963)		14,557		10,427	_	(4,086)		24,925
Less: Net income attributable to non-controlling		(22,500)		11,007		10,127		(1,000)		21,520
interests		(3,774)		(2,859)		(2,434)		(3,220)		(983)
Net (loss)/income attributable to the company	-	(26,737)	_	11,698	Ξ	7,993	Τ	(7,306)		23,942
Accretion on redeemable non-controlling interests	-	(20,707)	_		-	(43,001)	-	(25,510)	-	
	-		_		-	(43,001)	_	(23,310)	_	
Net (loss)/income attributable to ordinary shareholders of the company	\$	(26,737)	¢	11,698	\$	(35,008)	Ф	(32,816)	Ф	23,942
	φ	(20,737)	Ψ	11,070	φ	(33,000)	Ψ	(32,810)	Ф	23,742
(Losses)/earnings per share attributable to ordinary										
shareholders of the company—basic (\$ per share) Continuing operations	\$	(0.43)	\$	0.20	\$	(0.64)	¢	(0.64)	•	0.49
Discontinued operations	\$	(0.43)	\$	0.20	\$	(0.04)	\$	0.02		(0.03)
(Losses)/earnings per share attributable to ordinary	Ψ		Ψ		Ψ		Ψ	0.02	Ψ	(0.05)
shareholders of the company—diluted (\$ per share)										
Continuing operations	\$	(0.43)	\$	0.20	\$	(0.64)	\$	(0.64)	\$	0.44
Discontinued operations	\$	` —	\$	_	\$	` —	\$	0.02	\$	(0.03)
Number of shares used in per share calculation—basic		61,717,171		59,715,173		54,659,315		52,563,387		52,050,988
Number of shares used in per share calculation—diluted		61,717,171		59,971,050		54,659,315		52,563,387		52,878,426
Net (loss)/income	\$	(22,963)	\$	14,557	\$	10,427	\$	(4,086)	\$	24,925
Other comprehensive income/(loss): Foreign currency translation gain/(loss)		10,964		(10.722)		(5 557)		(2.712)		3,243
	_		_	(10,722)	_	(5,557)	_	(2,712)	_	
Total comprehensive (loss)/income		(11,999)		3,835		4,870		(6,798)		28,168
Less: Comprehensive income attributable to		/# 02=1		/* · · · ·		/- ===:		(2.24		(* ***
non-controlling interests		(5,033)	_	(1,427)		(1,732)		(2,944)		(1,296)
Total comprehensive (loss)/income attributable to the										
company	\$	(17,032)	\$	2,408	\$	3,138	\$	(9,742)	\$	26,872
	_		_							

	As of December 31,							
	2017	2016	2015	2014				
		(in thousands)						
Consolidated balance sheet data:								
Cash and cash equivalents	\$ 85,265	\$ 79,431	\$ 31,941	\$ 38,946				
Total assets	\$ 597,932	\$ 342,437	\$ 229,599	\$ 210,617				
Total current liabilities	\$ 104,600	\$ 95,119	\$ 81,062	\$ 75,299				
Total non-current liabilities	\$ 8,366	\$ 43,258	\$ 46,260	\$ 37,367				
Total shareholders' equity	\$ 484,966	\$ 204,060	\$ 102,277	\$ 56,915				

### Selected Financial Data of Our Non-Consolidated Joint Ventures

We have three non-consolidated joint ventures—Shanghai Hutchison Pharmaceuticals, Hutchison Baiyunshan and Nutrition Science Partners. The following selected consolidated comprehensive income and cash flow data of each such joint venture for the years ended December 31, 2017, 2016 and 2015 and the following selected consolidated statements of financial position of each such joint venture as of December 31, 2017 and 2016 have been derived from their respective audited consolidated financial statements, which were prepared in accordance with IFRS as issued by the IASB and are included elsewhere in this annual report. You should read this data together with such consolidated financial statements of our non-consolidated joint ventures and the related notes and Item 5 "Operating and Financial Review and Prospects." The following selected consolidated financial data for the years ended December 31, 2014 and 2013 and as of December 31, 2015 and 2014 have been derived from their respective audited consolidated financial statements, which were prepared in accordance with IFRS as issued by the IASB and are not included in this annual report. The historical results of our joint ventures for any prior period are not necessarily indicative of results to be expected in any future periods.

### Shanghai Hutchison Pharmaceuticals

	Year Ended December 31,									
	2017 2016		2015 2014		2013					
			(in thousands)							
Income statement and cash flow data:										
Revenue	\$ 244,557	\$ 222,368	\$ 181,140	\$ 154,703	\$ 138,160					
Profit for the year	\$ 55,623	\$ 120,499	\$ 31,307	\$ 26,402	\$ 22,424					
Dividends paid to shareholders	\$ (81,299)	\$ (55,057)	\$ (6,410)	\$ (19,077)	\$ (17,162)					

Our equity in earnings of Shanghai Hutchison Pharmaceuticals reported under U.S. GAAP was \$27.8 million, \$60.3 million, \$15.7 million, \$13.2 million and \$11.2 million for the years ended December 31, 2017, 2016, 2015, 2014 and 2013, respectively.

		As of December 31,							
	2017	2016 2015		2014					
		(in thousands)							
Financial position data:									
Cash and cash equivalents	\$ 43,527	\$ 20,292	\$ 43,141	\$ 16,575					
Total assets	\$ 233,012	\$ 244,006	\$ 224,969	\$ 143,174					
Total liabilities	\$ 100,281	\$ 93,872	\$ 131,706	\$ 71,268					
Total shareholders' equity	\$ 132,731	\$ 150,134	\$ 93,263	\$ 71,906					

	Year Ended December 31,									
	2017	2016	2015	2014	2013					
			(in thousands)	)						
Income statement and cash flow data:										
Revenue	\$ 227,422	\$ 224,131	\$ 211,603	\$ 243,746	\$ 247,626					
Profit for the year	\$ 20,805	\$ 20,128	\$ 21,216	\$ 20,865	\$ 17,361					
Profit for the year attributable to shareholders										
of Hutchison Baiyunshan	\$ 20,776	\$ 20,376	\$ 21,376	\$ 20,775	\$ 17,165					
Dividends paid to shareholders	\$ (29,872)*	\$ (6,000)	\$ (6,410)	\$ (12,820)	\$ (6,462)					

<sup>\*</sup> Dividends paid to shareholders exclude an additional \$15.3 million of dividends declared but unpaid as of December 31, 2017.

Our equity in earnings of Hutchison Baiyunshan reported under U.S. GAAP was \$10.4 million, \$10.2 million, \$10.7 million, \$10.4 million and \$8.6 million for the years ended December 31, 2017, 2016, 2015, 2014 and 2013, respectively.

	As of December 31,							
	2017 2016		2015	2014				
	(in thousands)							
Financial position data:								
Cash and cash equivalents	\$ 13,843	\$ 23,448	\$ 31,155	\$ 31,004				
Total assets	\$ 208,796	\$ 221,735	\$ 202,646	\$ 217,171				
Total liabilities	\$ 94,535	\$ 88,366	\$ 77,583	\$ 101,863				
Total shareholders' equity	\$ 114,261	\$ 133,369	\$ 125,063	\$ 115,308				

Nutrition Science Partners

	Year Ended December 31,									
		2017		2016		2015	20	14		2013
	(in thousands)									
Income statement data:										
Revenue	\$	_	\$	_	\$	_	\$	_	\$	_
Loss for the year	\$	(9,210)	\$	(8,482)	\$	(7,552)	\$ (16	,812)	\$	(17,543)

Our equity in loss of Nutrition Science Partners reported under U.S. GAAP was \$4.6 million, \$4.2 million, \$3.8 million, \$8.4 million and \$8.8 million for the years ended December 31, 2017, 2016, 2015, 2014 and 2013, respectively.

	As of December 31,									
	2017		2016		2015		2014			
	(in thousands)									
Financial position data:										
Cash and cash equivalents	\$	9,640	\$	5,393	\$	2,624	\$	6,249		
Total assets	\$	39,640	\$	35,393	\$	33,034	\$	38,548		
Total liabilities	\$	1,239	\$	1,782	\$	14,941	\$	12,903		
Total shareholders' equity	\$	38,401	\$	33,611	\$	18,093	\$	25,645		

### B. Capitalization and Indebtedness.

Not applicable.

### C. Reasons for the Offer and Use of Proceeds.

Not applicable.

#### D. Risk Factors.

### Risks Related to Our Financial Position and Need for Capital

We may need substantial funding for our product development programs and commercialization efforts. If we are unable to raise capital on acceptable terms when needed, we could incur losses and be forced to delay, reduce or eliminate such efforts.

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we or our collaboration partners advance the clinical development of our eight clinical drug candidates which are currently in active or completed clinical studies in 36 target patient populations in various countries, including six Phase III studies on savolitinib, fruquintinib and sulfatinib, and continue research and development and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. In addition, if we obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs that may be required for the manufacture of any drug candidate that receives regulatory approval may be substantial as we may have to modify or increase the production capacity at our current manufacturing facilities or contract with third-party manufacturers. We may also incur expenses as we create additional infrastructure to support our operations as a U.S. public company. Accordingly, we may need to obtain substantial funding in connection with our continuing operations through public or private equity offerings, debt financings, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on attractive terms, we could incur losses and be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our expected cashflow from operations (including from our Commercial Platform and milestone and other payments from our collaboration partners) and our cash and cash equivalents as of December 31, 2017, as well as (i) the HK\$234.0 million (\$30.0 million) revolving credit facility with The Hongkong and Shanghai Banking Corporation Limited, or HSBC, (ii) the aggregate HK\$351.0 million (\$45.0 million) in credit facilities entered into with Bank of America N.A., (iii) the aggregate HK\$195.0 million (\$25.0 million) in credit facilities entered into with Deutsche Bank AG, Hong Kong Branch and (iv) the HK\$210.0 million (\$26.9 million) three-year term loan and HK\$190.0 million (\$24.4 million) 18-month revolving loan facility from Scotiabank (Hong Kong) Limited, or Scotiabank, will enable us to fund our operating expenses, debt service and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the number and development requirements of the drug candidates we pursue;
- the scope, progress, timing, results and costs of researching and developing our drug candidates, and conducting pre-clinical and clinical trials;
- the cost, timing and outcome of regulatory review of our drug candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approval;
- the amount and timing of any milestone payments from our collaboration partners, with whom we cooperate with respect to the development and potential commercialization of certain of our drug candidates;
- the cash received, if any, received from commercial sales of any drug candidates for which we receive regulatory approval;

- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims:
- · our headcount growth and associated costs; and
- the costs of operating as a public company in the United States and on the AIM market.

Identifying potential drug candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that may take years to complete, and our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available until we receive regulatory approval, if at all. We may never generate the necessary data or results required to obtain regulatory approval and achieve product sales, and even if one or more of our drug candidates is approved, they may not achieve commercial success. Accordingly, we will need to continue to rely on financing to achieve our business objectives. Adequate financing may not be available to us on acceptable terms, or at all.

### If the CK Hutchison group ceases to own a majority stake in our company, we may incur significantly higher borrowing costs.

Hutchison Whampoa Limited, a wholly owned subsidiary of CK Hutchison, has historically guaranteed certain of our bank borrowings. The CK Hutchison group does not currently guarantee any of our loans and has no obligation to enter into new guarantees in the future. CK Hutchison has, however, issued letters of awareness to certain of our current lenders and committed not to reduce its shareholding to less than 40% of our issued share capital while such loans are outstanding. We may incur higher funding costs if we do not have the benefit of the CK Hutchison group guarantees or other similar arrangements by the CK Hutchison group.

### Raising capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to technologies or drug candidates.

We expect to finance our cash needs in part through cash flow generated by our Commercial Platform, and we may also rely on raising capital through a combination of public or private equity offerings, debt financings and/or license and development agreements with collaboration partners. In addition, we may seek capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our existing shareholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional debt financing would also result in increased fixed payment obligations.

In addition, if we raise funds through collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us. We may also lose control of the development of drug candidates, such as the pace and scope of clinical trials, as a result of such third-party arrangements. If we are unable to raise funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

### Our existing and any future indebtedness could adversely affect our ability to operate our business.

Our outstanding indebtedness combined with current and future financial obligations and contractual commitments, including any additional indebtedness beyond our current facilities with HSBC, Scotiabank, Bank of America N.A. and Deutsche Bank AG could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, and prepayment and repayment fees and penalties, thereby reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and short-term investments. Nevertheless, we may not have sufficient funds, and may be unable to arrange for financing, to pay the amounts due under our existing debt. Failure to make payments or comply with other covenants under our existing debt instruments could result in an event of default and acceleration of amounts due.

#### Risks Related to Our Innovation Platform

Historically, our in-house research and development division, known as our Innovation Platform, has not generated significant profits or has operated at a net loss.

We do not expect our Innovation Platform to be significantly profitable unless and until we obtain regulatory approval of, and begin to sell, one or more of our drug candidates. We expect to incur significant sales and marketing costs as we prepare to commercialize our drug candidates. Even if we initiate and successfully complete clinical trials of our drug candidates, and our drug candidates are approved for commercial sale, and despite expending these costs, our drug candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever.

If we are unable to generate drug sales, we will not become profitable and may be unable to continue operations without continued funding.

All of our drug candidates are still in development. If we are unable to obtain regulatory approval and ultimately commercialize our drug candidates or experience significant delays in doing so, our business will be materially harmed.

All of our drug candidates are still in development including eight in clinical development. In June 2017, we completed our first new drug application, or NDA, submission in China, which was for fruquintinib in patients with third-line colorectal cancer. Although we and our joint venture Nutrition Science Partners receive certain payments from our collaboration partners, including upfront payments and payments for achieving certain development, regulatory or commercial milestones, for certain of our drug candidates, our ability to generate revenue from our drug candidates is dependent on their receipt of regulatory approval for and successfully commercializing such products, which may never occur. Each of our drug candidates will require additional pre-clinical and/or clinical development, regulatory approval in multiple jurisdictions, manufacturing supply, substantial investment and significant marketing efforts

before we generate any revenue from product sales. The success of our drug candidates will depend on several factors, including the following:

- successful completion of pre-clinical and/or clinical studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations;
- successful completion of all safety studies required to obtain regulatory approval in the United States, China and other jurisdictions for our drug candidates;
- adapting our commercial manufacturing capabilities to the specifications for our drug candidates for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our drug candidates;
- launching commercial sales of our drug candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of the drug candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- · enforcing and defending intellectual property rights and claims; and
- · maintaining a continued acceptable safety profile of the drug candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business.

Our primary approach to the discovery and development of drug candidates focuses on the inhibition of kinases, some of which are unproven, and we do not know whether we will be able to develop any products of commercial value.

A primary focus of our research and development efforts is on identifying kinase targets for which drug compounds previously developed by others affecting those targets have been unsuccessful due to limited selectivity, off-target toxicity and other problems. We then work to engineer drug candidates which have the potential to have superior efficacy, safety and other features as compared to such prior drug compounds. We also focus on developing drug compounds with the potential to be global best-in-class/next-generation therapies for validated kinase targets.

Even if we are able to develop compounds that successfully target the relevant kinases in pre-clinical studies, we may not succeed in demonstrating safety and efficacy of the drug candidates in clinical trials. As a result, our efforts may not result in the discovery or development of drugs that are commercially viable or are superior to existing drugs or other therapies on the market. While the results of pre-clinical studies and early-stage clinical trials have suggested that certain of our drug candidates may successfully inhibit kinases and may have significant utility in several cancer indications, potentially in combination with other cancer drugs and with chemotherapy, we have not yet demonstrated efficacy and safety for most of our drug candidates in later stage clinical trials.

In addition, we have not yet had a drug candidate receive approval or clearance from the U.S. Food and Drug Administration, or FDA, the China Food and Drug Administration, or CFDA, or another

regulatory authority. While the FDA and CFDA have approved kinases inhibitors before, the regulatory review process for our drug candidates is uncertain, and we may be required to conduct additional studies or trials beyond those we anticipate resulting in a longer regulatory approval pathway.

# We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must limit our research programs to specific drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

## We have no history of commercializing our internally developed drugs, which may make it difficult to evaluate our future prospects.

The operations of our Innovation Platform have been limited to developing and securing our technology and undertaking pre-clinical studies and clinical trials of our drug candidates, either independently or with our collaboration partners. We have not yet demonstrated the ability to successfully complete development of any drug candidates, obtain marketing approvals, manufacture our internally developed drugs at a commercial scale, or conduct sales and regulatory activities necessary for successfully product commercialization of our drug candidates. While we believe we will be able to successfully leverage our existing Commercial Platform to manufacture, sell and market our drug candidates in China once approved, any predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing our internally developed pharmaceutical products.

# The regulatory approval processes of the FDA, CFDA and comparable authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our ability to generate revenue will be materially impaired.

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA, CFDA and other regulatory agencies in the United States and China and by comparable authorities in other countries. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals in the United States, China and other countries is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each

submitted NDA, pre-market approval or equivalent application types, may cause delays in the approval or rejection of an application. The FDA, CFDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical, clinical or other studies. Our drug candidates, including fruquintinib for which we submitted our first NDA in June 2017, could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA, CFDA or comparable regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, CFDA or comparable regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, CFDA or comparable regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA, CFDA or comparable regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA, CFDA or comparable regulatory authorities may fail to approve the manufacturing processes for our clinical and commercial supplies;
- the approval policies or regulations of the FDA, CFDA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- the FDA, CFDA or comparable regulatory authorities may restrict the use of our products to a narrow population; and
- our collaboration partners or CROs that are retained to conduct the clinical trials of our drug candidates may take actions that materially and adversely impact the clinical trials.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

If the FDA, CFDA or another regulatory agency revokes its approval of, or if safety, efficacy, manufacturing or supply issues arise with, any therapeutic that we use in combination with our drug candidates, we may be unable to market such drug candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We are currently focusing on the clinical development of savolitinib as both a monotherapy and in combination with immunotherapy Imfinzi (durvalumab), targeted therapies (Tagrisso (osimertinib) and Iressa (gefitinib)) and chemotherapy (Taxotere (docetaxel)). We are also focusing on the clinical development of our drug candidate fruquintinib as both a monotherapy and in combination with chemotherapy (Taxol (paclitaxel)) and targeted therapies (Iressa (gefitinib)), and may focus on additional combinations in the future. However, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, Tagrisso, Iressa, Taxotere, Taxol or Imfinzi or any other therapeutic we use in

combination with our drug candidates. We may also seek to develop our drug candidates in combination with other therapeutics in the future.

If the FDA, CFDA or another regulatory agency revokes its approval of any of Tagrisso, Iressa, Taxotere, Taxol, Imfinzi or another therapeutic we use in combination with our drug candidates, we will not be able to market our drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of Tagrisso, Iressa, Taxotere, Taxol, Imfinzi or any other combination therapeutics, we may not be able to complete clinical development of savolitinib, fruquintinib and/or another of our drug candidates on our current timeline or at all.

Even if one or more of our drug candidates were to receive regulatory approval for use in combination with Tagrisso, Iressa, Taxotere, Taxol, Imfinzi or another therapeutic, we would continue to be subject to the risk that the FDA, CFDA or another regulatory agency could revoke its approval of the combination therapeutic, or that safety, efficacy, manufacturing or supply issues could arise with one of these combination therapeutics. This could result in savolitinib, fruquintinib or one of our other products being removed from the market or being less successful commercially.

## We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market drugs or are pursuing the development of therapies in the field of kinase inhibition for cancer and other diseases. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Specifically, there are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA, CFDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of

our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

### Clinical development involves a lengthy and expensive process with an uncertain outcome.

There is a risk of failure for each of our drug candidates. It is difficult to predict when or if any of our drug candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any drug candidate, we or our collaboration partners must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement and can take many years to complete. The outcomes of pre-clinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates. Our current or future clinical trials may not be successful.

Commencing each of our clinical trials is subject to finalizing the trial design based on ongoing discussions with the FDA, CFDA or other regulatory authorities. The FDA, CFDA and other regulatory authorities could change their position on the acceptability of our trial designs or clinical endpoints, which could require us to complete additional clinical trials or impose approval conditions that we do not currently expect. Successful completion of our clinical trials is a prerequisite to submitting an NDA or analogous filing to the FDA, CFDA or other regulatory authorities for each drug candidate and, consequently, the ultimate approval and commercial marketing of our drug candidates. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

# We and our collaboration partners may incur additional costs or experience delays in completing our pre-clinical or clinical trials, or ultimately be unable to complete the development and commercialization of our drug candidates.

We and our collaboration partners, including AstraZeneca, Eli Lilly and Nestlé Health Science, may experience delays in completing our pre-clinical or clinical trials, and numerous unforeseen events could arise during, or as a result of, future clinical trials, which could delay or prevent us from receiving regulatory approval, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or we may fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, who conduct clinical trials on behalf of us and our collaboration partners, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we or our collaboration partners may decide, or regulators may require us or them, to conduct additional clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we or our collaboration partners add new clinical trial sites or investigators;

- we or our collaboration partners may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our drug candidates.

We could encounter regulatory delays if a clinical trial is suspended or terminated by us or our collaboration partners, by, as applicable, the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, which is an independent group of experts that is formed to monitor clinical trials while ongoing, or by the FDA, CFDA or other regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including: a failure to conduct the clinical trial in accordance with regulatory requirements or the applicable clinical protocols, inspection of the clinical trial operations or trial site by the FDA, CFDA or other regulatory authorities that results in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the FDA, CFDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

If we or our collaboration partners are required to conduct additional clinical trials or other testing of our drug candidates beyond those that are currently contemplated, if we or our collaboration partners are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the drug removed from the market after obtaining regulatory approval.

Our drug development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and may harm our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and prospects significantly.

If we or our collaboration partners experience delays or difficulties in the enrollment of patients in clinical trials, the progress of such clinical trials and our receipt of necessary regulatory approvals could be delayed or prevented.

We or our collaboration partners may not be able to initiate or continue clinical trials for our drug candidates if we or our collaboration partners are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, CFDA or similar regulatory authorities. In particular, we and our collaboration partners have designed many of our clinical trials, and expect to design future trials, to include some patients with the applicable genomic alteration that causes the disease with a view to assessing possible early evidence of potential therapeutic effect. Genomically defined diseases, however, may have relatively low prevalence, and it may be difficult to identify patients with the applicable genomic alteration. In addition, for our fruquintinib trials, we focus on enrolling patients who have failed their first or second-line treatments, which limits the total size of the patient population available for such trials. The inability to enroll a sufficient number of patients with the applicable genomic alteration or that meet other applicable criteria for our clinical trials would result in significant delays and could require us or our collaboration partners to abandon one or more clinical trials altogether.

In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- the total size and nature of the relevant patient population;
- the design and eligibility criteria for the clinical trial in question;
- the availability of an appropriate genomic screening test;
- the perceived risks and benefits of the drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the availability of competing therapies which are undergoing clinical trials;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which could cause the value of our company to decline and limit our ability to obtain financing.

Our drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.

Undesirable side effects caused by our drug candidates could cause us or our collaboration partners to interrupt, delay or halt clinical trials or could cause regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, CFDA or other regulatory authorities. In particular, as is the case with all oncology drugs, it is likely that there may be side effects, for example, hand-foot syndrome, associated with the use of certain of our drug candidates. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA, CFDA or comparable regulatory authorities could order us to cease further development of or deny approval of our

drug candidates for some or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our drug candidates could cause undesirable side effects related to off-target toxicity. Many of the currently approved tyrosine kinase inhibitors have been associated with off-target toxicities because they affect multiple kinases. While we believe that the kinase selectivity of our drug candidates has the potential to significantly improve the unfavorable adverse off-target toxicity issues, if patients were to experience off-target toxicity, we may not be able to achieve an effective dosage level, receive approval to market, or achieve the commercial success we anticipate with respect to any of our drug candidates, which could prevent us from ever generating revenue or achieving profitability. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Clinical trials assess a sample of the potential patient population. With a limited number of patients and duration of exposure, rare and severe side effects of our drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If our drug candidates receive regulatory approval and we or others identify undesirable side effects caused by such drug candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such drug candidates;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contra-indication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such drug candidates are distributed or administered, conduct additional clinical trials or change the labeling of the drug candidates;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy, or REMS, plan to
  mitigate risks, which could include medication guides, physician communication plans, or elements
  to assure safe use, such as restricted distribution methods, patient registries and other risk
  minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drug candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected drug candidates and could substantially increase the costs of commercializing our drug candidates, if approved, and significantly impact our ability to successfully commercialize our drug candidates and generate revenue.

We and our collaboration partners have conducted and intend to conduct additional clinical trials for certain of our drug candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or may require additional U.S.-based trials.

We and our collaboration partners have conducted, currently are conducting and intend in the future to conduct, clinical trials outside the United States, particularly in China where our Innovation Platform is headquartered as well as in Australia, Canada, Korea, U.K. and Spain.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted by qualified investigators in accordance with current good clinical practices, or GCPs, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside of the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials of fruquintinib, sulfatinib, epitinib or theliatinib in China, savolitinib in the U.K., Spain, South Korea, Canada and China, or HMPL-523, HMPL-689 and HMPL-453 in Australia and China, for example, or any other trial that we or our collaboration partners conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our ability to develop and market these or other drug candidates in the United States.

In addition, there are risks inherent in conducting clinical trials in jurisdictions outside the United States including:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that patient populations in such trials are not considered representative as compared to patient populations in the United States and other markets.

A Breakthrough Therapy designation by the FDA may not be granted to any of our drug candidates, and even if granted, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug candidates will receive regulatory approval.

We intend to seek Breakthrough Therapy designation in the United States for some of our drug candidates, including savolitinib in patients with papillary renal cell carcinoma, non-small cell lung cancer and gastric cancer, sulfatinib in patients with neuroendocrine tumors and possibly epitinib in patients with non-small cell lung cancer with brain metastasis. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of

patients placed in ineffective control regimens. Drugs designated as Breakthrough Therapies by the FDA are also eligible for accelerated approval.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as Breakthrough Therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification.

If we are unable to obtain and/or maintain CFDA approval for our drug candidates to be eligible for an expedited registration pathway, the time and cost we incur to obtain regulatory approvals may increase. Even if we receive such approvals, they may not lead to a faster development, review or approval process.

Under the Special Examination and Approval of the Registration of New Drugs provisions, the CFDA may grant "green-channel" approval to (i) active ingredients and their preparations extracted from plants, animals and minerals, and newly discovered medical materials and their preparations that have not been sold in the China market, (ii) chemical drugs and their preparations and biological products that have not been approved for sale at its origin country or abroad, (iii) new drugs with obvious clinical treatment advantages for diseases such as AIDS, therioma, and rare diseases, and (iv) new drugs for diseases that have not been treated effectively. We have achieved green-channel approval from the CFDA for savolitinib, fruquintinib, sulfatinib, epitinib and theliatinib. We anticipate that we may seek a green-channel development pathway for certain of our other drug candidates and indications. If granted, the green-channel will enable us to establish streamlined communication with the relevant review panel of the CFDA, thus improving the efficiency of new drug approval.

A failure to obtain and/or maintain green-channel approval or any other form of expedited development, review or approval for our drug candidates would result in a longer time period to commercialization of such drug candidate, could increase the cost of development of such drug candidate and could harm our competitive position in the marketplace. In addition, even if we obtain green-channel approval, there is no guarantee that we will experience a faster development process, review or approval compared to non-accelerated registration pathways or that a drug candidate will ultimately be approved for sale.

Even if we receive regulatory approval for any of our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense.

If the FDA, CFDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or GMPs, and GCPs. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the drug.

In addition, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able

to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any of our drugs that receive regulatory approval.

Once a drug is approved by the FDA, CFDA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA, CFDA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- · drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. If we or our collaborators are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

The incidence and prevalence for target patient populations of our drug candidates are based on estimates and third-party sources. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including determining indications on which to focus in pre-clinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, their acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

## Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the expertise of the members of our research and development team, as well as the other principal members of our management, including Christian Hogg, our Chief Executive Officer and director, and Weiguo Su, Ph.D., our Chief Scientific Officer and director. Although we have entered into employment agreements with our executive officers, each of them may terminate their

employment with us at any time with three months' prior written notice. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified management, scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

#### Risks Related to Our Commercial Platform

As a significant portion of our Commercial Platform business, which consists of our Prescription Drugs and Consumer Health divisions, is conducted through joint ventures, we are largely dependent on the success of our joint ventures and our receipt of dividends or other payments from our joint ventures for cash to fund our operations.

We are party to joint venture agreements with Shanghai Pharmaceuticals and Guangzhou Baiyunshan, relating to our non-consolidated joint ventures, which together form part of our Commercial Platform business. Our equity in the earnings of these non-consolidated joint ventures was \$26.3 million, \$70.5 million and \$38.2 million for the years ended December 31, 2015, 2016 and 2017, respectively, as recorded in our consolidated financial statements. Furthermore, we have consolidated joint ventures with each of Sinopharm and Hain Celestial which accounted for substantially all of our Commercial Platform's consolidated revenue for the years ended December 31, 2015, 2016 and 2017.

As a result, our ability to fund our operations and pay our expenses or to make future dividend payments, if any, is largely dependent on the earnings of our joint ventures and the payment of those earnings to us in the form of dividends. Payments to us by our joint ventures will be contingent upon our joint ventures' earnings and other business considerations and may be subject to statutory or contractual restrictions. Each joint venture's ability to distribute dividends to us is subject to approval by their respective boards of directors, which in the case of Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan are comprised of an equal number of representatives from each party.

Operationally, our joint venture partners have certain responsibilities and/or certain rights to exercise control or influence over operations and decision-making under the joint venture arrangements. Therefore, the success of our joint ventures depends on the efforts and abilities of our joint venture parties to varying degrees. For example, we share the ability to appoint the general manager of our joint venture with Guangzhou Baiyunshan, with each of us having a rotating four-year right, and therefore, our ability to manage the day-to-day operations of this joint venture is more limited. On the other hand, we appoint the general managers of Hutchison Sinopharm and Shanghai Hutchison Pharmaceuticals pursuant to the respective joint venture agreements governing these entities and therefore oversee the day-to-day management of these joint ventures. However, we still rely on our joint venture partners Sinopharm and Shanghai Pharmaceuticals to provide certain distribution and logistics services. See "—Risks Related to our Dependence on Third Parties—Joint ventures form an important part of our Commercial Platform business, and our ability to manage and develop the businesses conducted by these joint ventures depends in part on our relationship with our joint venture partners" for more information.

We intend to use our Commercial Platform's Prescription Drugs business to commercialize our internally developed drug candidates, but we may not be successful in adapting this business to successfully manufacture, sell and market our drug candidates if and when they are approved, and we may not be able to generate any revenue from such products.

Our Prescription Drugs business is operated by our Shanghai Hutchison Pharmaceuticals and Hutchison Sinopharm joint ventures and currently has a manufacturing, sales and marketing infrastructure in China. If our drug candidates are approved, we intend to leverage our Prescription Drugs business to commercialize such drug candidates; however, to do so, we must adapt our Prescription Drugs business to cater to oncology and/or immunology drug sales to achieve commercial success for any approved drug candidate in these areas. In the future, we may need to expand the sales and marketing team of these joint ventures or refocus their activities to some of our drug candidates if and when they are approved.

There are risks involved with adapting our current Prescription Drugs business. For example, recruiting and/or training a sales force in new therapeutic areas is time consuming and could delay any drug launch. Factors that may inhibit our efforts to commercialize our drug candidates through our Prescription Drugs business include:

- our joint ventures' inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of our joint ventures' sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs; and
- the lack of complementary drugs to be offered by our joint ventures' sales personnel, which may put our joint ventures at a competitive disadvantage relative to companies with more extensive product lines.

In such case, our business, results of operations, financial condition and prospects will be materially and adversely affected.

### Our Commercial Platform faces substantial competition.

Our Commercial Platform's Prescription Drugs business competes in the pharmaceutical industry in China, which is characterized by a number of established, large pharmaceutical companies, as well as some smaller emerging pharmaceutical companies. Our Prescription Drugs business competes with pharmaceutical companies engaged in the development, production, marketing or sales of prescription drugs, in particular cardiovascular drugs. The identities of the key competitors with respect to our Prescription Drugs business vary by product and, in certain cases, competitors have greater financial resources than us and may elect to focus these resources on developing, importing or in-licensing and marketing products in the PRC that are substitutes for our products and may have broader sales and marketing infrastructure with which to do so. Our Commercial Platform's Consumer Health business also competes in a highly fragmented market in Asia.

The products sold through our Commercial Platform, which may include our drug candidates if they receive regulatory approval, may compete against products that have lower prices, superior performance, greater ease of administration or other advantages compared to our products. In some circumstances, price competition may drive our competitors to conduct illegal manufacturing processes to lower their manufacturing costs. Increased competition may result in price reductions, reduced margins and loss of market share, whether achieved by either legal or illegal means, any of which could materially and adversely affect our profit margins. We and our joint ventures may not be able to compete effectively against current and future competitors.

### If we are not able to maintain and enhance brand recognition of the Commercial Platform's products to maintain its competitive advantage, our reputation, business and operating results may be harmed.

We believe that market awareness of the products sold through our Commercial Platform, which include our joint ventures' branded products, such as Baiyunshan and Shang Yao, and the brands of third-party products which are distributed through our joint ventures, such as AstraZeneca's Seroquel, has contributed significantly to the success of our Commercial Platform. We also believe that maintaining and enhancing such brands is critical to maintaining our competitive advantage. Although the sales and marketing staff of our Commercial Platform will continue to further promote such brands to remain competitive, they may not be successful. If our joint ventures are unable to further enhance brand recognition and increase awareness of their products, or if they are compelled to incur excessive marketing and promotion expenses in order to maintain brand awareness, our business and results of operations may be materially and adversely affected. Furthermore, our results of operations could be adversely affected if the Baiyunshan and Shang Yao brands, or the brands of any other products, or our reputation, are impaired by certain actions taken by our joint venture partners, distributors, competitors or relevant regulatory authorities.

### Reimbursement may not be available for the products currently sold through our Commercial Platform or our drug candidates in China, the United States or other countries, which could diminish our sales or affect our profitability.

The regulations that govern pricing and reimbursement for pharmaceuticals vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after regulatory approval is granted. In some foreign markets, pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Furthermore, once marketed and sold, government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Adverse pricing reimbursement levels may hinder market acceptance of products sold by our Commercial Platform or drug candidates.

In China, for example, the Ministry of Human Resources and Social Security of the PRC or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the PRC's National Medical Insurance Catalogue or provincial or local medical insurance catalogues for the National Medical Insurance Program every other year, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those medicines. These determinations are made based on a number of factors, including price and efficacy. Depending on the tier under which a drug is classified in the provincial medicine catalogue, a National Medical Insurance Program participant residing in that province can be reimbursed for the full cost of Tier 1 medicine and for the majority of the cost of a Tier 2 medicine. In some instances, if the price range designated by the local or provincial government decreases, it may adversely affect our business and could reduce our total revenue, and if our revenue falls below production costs, we may stop manufacturing certain products. In addition, in order to access certain local or provincial-level markets, our joint ventures are periodically required to enter into competitive bidding processes for She Xiang Bao Xin pills (the best-selling product of our Shanghai Hutchison Pharmaceuticals joint venture), Fu Fang Dan Shen tablets (the best-selling product of our Hutchison Baiyunshan joint venture) and other products with a pre-defined price range. The competitive bidding in effect sets price ceilings for those products, thereby limiting our profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs which may affect reimbursement rates of our drug candidates if approved. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers. The Affordable Care Act, among other things, subjects biologic products to potential competition by lower-cost biosimilars and establishes annual

fees and taxes on manufacturers of certain branded prescription drugs. It also establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted.

Modifications to or repeal of all or certain provisions of the Healthcare Reform Act are expected as a result of the outcome of the 2016 presidential election and Republicans maintaining control of Congress, consistent with statements made by President Donald Trump and members of Congress during the presidential campaign and following the election. We cannot predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results. We expect that additional U.S. state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures. We expect that the pharmaceutical industry will experience pricing pressures due to the increasing influence of managed care (and related implementation of managed care strategies to control utilization), additional federal and state legislative and regulatory proposals to regulate pricing of drugs, limit coverage of drugs or reduce reimbursement for drugs, public scrutiny and the Trump administration's agenda to control the price of pharmaceuticals through government negotiations of drug prices in Medicare Part D and importation of cheaper products from abroad.

Moreover, eligibility for reimbursement in the United States does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim U.S. reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by U.S. government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

# Sales of products sold by our Prescription Drugs business rely on the ability to win tender bids for the medicine purchases of hospitals in China.

Our Commercial Platform's Prescription Drugs business markets to hospitals in China who may make bulk purchases of a medicine only if that medicine is selected under a government-administered tender process. Periodically, a bidding process is organized on a provincial or municipal basis. Whether a drug manufacturer is invited to participate in the tender depends on the level of interest that hospitals have in purchasing this drug. The interest of a hospital in a medicine is evidenced by:

- the inclusion of this medicine on the hospital's formulary, which establishes the scope of drug physicians at this hospital may prescribe to their patients, and
- the willingness of physicians at this hospital to prescribe a particular drug to their patients.

We believe that effective marketing efforts are critical in making and keeping hospitals interested in purchasing the Prescription Drugs sold through our Commercial Platform so that we and our joint ventures are invited to submit the products to the tender. Even if we and our joint ventures are invited to do so, competitors may be able to substantially reduce the price of their products or services. If competitors are able to offer lower prices, our and our joint ventures' ability to win tender bids during the hospital tender process will be materially affected, and could reduce our total revenue or decrease our profit.

# Counterfeit products in China could negatively impact our revenue, brand reputation, business and results of operations.

Our Commercial Platform's products are subject to competition from counterfeit products, especially counterfeit pharmaceuticals which are manufactured without proper licenses or approvals and are fraudulently mislabeled with respect to their content and/or manufacturer. Counterfeiters may illegally manufacture and market products under our or our joint venture's brand names, the brand names of the third-party products we or they sell, or those of our or their 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 or our joint ventures' brand names or the brand names of third-party products we or they sell result in adverse side effects to consumers, we or our joint ventures may be associated with any negative publicity resulting from such incidents. In addition, consumers may buy counterfeit pharmaceuticals that are in direct competition with the products sold through our Commercial Platform, which could have an adverse impact on our revenue, business and results of operations. The proliferation of counterfeit pharmaceuticals in China and globally may 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 revenue, brand reputation, business and results of operations.

Pharmaceutical companies in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our and our joint ventures' ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on the Commercial Platform business.

The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including approval, production, distribution, advertising, licensing and certification requirements and procedures, periodic renewal and reassessment processes, registration of new drugs and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business. In order to manufacture and distribute pharmaceutical products in China, we and our joint ventures are required to:

- obtain a pharmaceutical manufacturing permit and GMP certificate for each production facility from the relevant food and drug administrative authority;
- obtain a drug registration certificate, which includes a drug approval number, from the CFDA for each drug manufactured by us;
- obtain a pharmaceutical distribution permit and good supply practice, or GSP, certificate from the CFDA; and
- renew the pharmaceutical manufacturing permits, the pharmaceutical distribution permits, drug registration certificates, GMP certificates and GSP certificates, among other requirements.

If we or our joint ventures are unable to obtain or renew such permits or any other permits or licenses required for our or their operations, we will not be able to engage in the manufacture and distribution of our products and our business may be adversely affected.

The regulatory framework regarding the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and results of operations. The PRC government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the reform still remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the level we expect, if at all. Moreover, the reform could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

For further information regarding government regulation in China and other jurisdictions, see Item 4.B. "Business Overview—Regulation—Government Regulation of Pharmaceutical Product Development and Approval," "Business Overview—Regulation—Coverage and Reimbursement" and "Business Overview—Regulation—Other Healthcare Laws."

### Rapid changes in the pharmaceutical industry may render our Commercial Platform's current products or our drug candidates obsolete.

Future technological improvements by our competitors and continual product developments in the pharmaceutical market may render our and our joint ventures' existing products, our or their third-party licensed products or our drug candidates obsolete or affect our Commercial Platform's viability and competitiveness. Therefore, our Commercial Platform's future success will largely depend on our and our joint ventures' ability to:

- improve existing products;
- develop innovative drug candidates;
- diversify the product and drug candidate portfolio;
- license diverse third-party products; and
- develop new and competitively priced products which meet the requirements of the constantly changing market.

If we or our joint ventures fail to respond to this environment by improving our Commercial Platform's existing products, licensing new third-party products or developing new drug candidates in a timely fashion, or if such new or improved products do not achieve adequate market acceptance, our business and profitability may be materially and adversely affected.

Our Commercial Platform's principal products involve the cultivation or sourcing of key raw materials including botanical products, and any quality control or supply failure or price fluctuations could adversely affect our Commercial Platform's ability to manufacture our products and/or could materially and adversely affect our operating results.

The key raw materials used in the manufacturing process of certain of our Commercial Platform's principal products are medicinal herbs whose properties are related to the regions and climatic conditions in which they are grown. Access to quality raw materials and products necessary for the manufacture of our Commercial Platform products is not guaranteed. We rely on a combination of materials grown by our or our joint ventures' entities and materials sourced from third-party growers and suppliers. The availability, quality and prices of these raw materials are dependent on and closely affected by weather conditions and other seasonal factors which have an impact on the yields of the harvests each year. The quality, in some instances, also depends on the operations of third-party growers or suppliers. There is a risk that such growers or suppliers sell or attempt to sell us or our joint ventures raw materials which are not authentic. If

there is any supply interruption for an indeterminate period of time, our joint ventures may not be able to identify and obtain alternative supplies that comply with our quality standards in a timely manner. Any supply disruption could adversely affect our ability to satisfy demand for our products, and materially and adversely affect our product sales and operating results. Moreover, any use by us or our joint ventures of unauthentic materials illegally sold to us by third-party growers or suppliers in our or our joint ventures' products may result in adverse side effects to the consumers, negative publicity, or product liability claims against us or our joint ventures, any of which may materially and adversely affect our operating results.

The prices of necessary raw materials and products may be subject to price fluctuations according to market conditions, and any sudden increases in demand in the case of a widespread illness such as SARS, MERS or avian flu may impact the costs of production. For example, the market price of Sanqi, one of the main natural raw materials in Hutchison Baiyunshan's Fu Fang Dan Shen tablets, fluctuated significantly between 2009 and 2017. Our Commercial Platform sources Sanqi and other necessary raw materials on a purchase order basis and does not have long-term supply contracts in place so that it can manage inventory levels to reduce its risk to price fluctuations; however, we cannot guarantee that we or our joint ventures will be successful. Raw material price fluctuations could increase the cost to manufacture our Commercial Platform's products and adversely affect our operating results.

# Adverse publicity associated with our company, our joint ventures or our or their products or third-party licensed products or similar products manufactured by our competitors could have a material adverse effect on our results of operations.

Sales of the Commercial Platform's products are highly dependent upon market perceptions of the safety and quality of our and our joint ventures' products and the third-party products we and they distribute. Concerns over the safety of biopharmaceutical products manufactured in China could have an adverse effect on the reputation of our industry and the sale of such products, including products manufactured or distributed by us and our joint ventures.

We could be adversely affected if any of our or our joint ventures' products, third-party licensed products or any similar products manufactured by other companies prove to be, or are alleged to be, harmful to patients. Any negative publicity associated with severe adverse reactions or other adverse effects resulting from patients' use or misuse of our and our joint ventures' products or any similar products manufactured by other companies could also have a material adverse impact on our results of operations. We and our joint ventures have not, to date, experienced any significant quality control or safety problems. If in the future we or our joint ventures become involved in incidents of the type described above, such problems could severely and adversely impact our financial position and reputation.

## We are dependent on our joint ventures' production facilities in Shanghai, Guangzhou and Bozhou, China for the manufacture of our principal Commercial Platform products.

The principal products sold by our Commercial Platform are mainly produced or expected to be produced at our joint ventures' manufacturing facilities in Shanghai, Guangzhou and Bozhou, China. A significant disruption at those facilities, even on a short-term basis, could impair our joint ventures' ability to timely produce and ship products, which could have a material adverse effect on our business, financial position and results of operations.

Our joint ventures' manufacturing operations are vulnerable to interruption and damage from natural and other types of disasters, including earthquake, fire, floods, environmental accidents, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our or our joint ventures' business at these facilities would be materially impaired. In addition, the nature of our production and research activities could cause significant delays in our programs and make it difficult for us to recover from a disaster. We and our joint ventures maintain insurance for business interruptions to

cover some of our potential losses; however, such disasters could still disrupt our operations and thereby result in substantial costs and diversion of resources.

In addition, our and our joint ventures' production process requires a continuous supply of electricity. We and they have encountered power shortages historically due to restricted power supply to industrial users during summers when the usage of electricity is high and supply is limited or as a result of damage to the electricity supply network. Because the duration of those power shortages was brief, they had no material impact on our or their operations. Interruptions of electricity supply could result in lengthy production shutdowns, increased costs associated with restarting production and the loss of production in progress. Any major suspension or termination of electricity or other unexpected business interruptions could have a material adverse impact on our business, financial condition and results of operations.

### Risks Related to our Dependence on Third Parties

Disagreements with our current or future collaboration partners, or the termination of any collaboration arrangement, could cause delays in our product development and materially and adversely affect our business.

Our collaborations with AstraZeneca, Eli Lilly and Nestlé Health Science and any future collaborations that we enter into may not be successful. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable drug candidate and, in some cases, termination of the collaboration arrangement. Because, among other things, we are much smaller than our collaboration partners and because they or their affiliates may sell competing products, our interests may not always be aligned. This may result in potential conflicts between our collaborators and us on matters that we may not be able to resolve on favorable terms or at all.

Collaborations with pharmaceutical or biotechnology companies and other third parties, including our existing agreements with AstraZeneca, Eli Lilly and Nestlé Health Science, are often terminable by the other party for any reason with certain advance notice. Any such termination or expiration would adversely affect us financially and could harm our business reputation. For instance, in the event one of the strategic alliances with a current collaborator is terminated, we may require significant time and resources to secure a new collaboration partner, if we are able to secure such an arrangement at all. As noted in the following risk factor, establishing new collaboration arrangements can be challenging and time-consuming. The loss of existing or future collaboration arrangements would not only delay or potentially terminate the possible development or commercialization of products we may derive from our technologies, but it may also delay or terminate our ability to test specific target candidates.

We rely on our collaborations with third parties for certain of our drug development activities, and, if we are unable to establish new collaborations when desired on commercially attractive terms or at all, we may have to alter our development and commercialization plans.

Certain of our drug development programs and the potential commercialization of certain drug candidates rely on collaborations with AstraZeneca, Eli Lilly and Nestlé Health Science. In the future, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of our other drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, CFDA or similar regulatory authorities outside the United States and China, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge

to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our drug candidate. The terms of any additional collaboration or other arrangements that we may establish may not be favorable to us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the drug candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate drug revenue.

Further development and commercialization of our own drug candidates will depend, in part, on strategic alliances with our collaborators. If our collaborators do not diligently pursue product development efforts, impeding our ability to collect milestone and royalty payments, our progress may be delayed and our revenue may be deferred.

We rely and expect to continue to rely, to some extent, on our collaborators to provide funding in support of our own independent research and pre-clinical and clinical testing. We do not currently possess the financial resources necessary to fully develop and commercialize each of our drug candidates or the resources or capabilities to complete the lengthy regulatory approval processes that may be required for our drug candidates. Therefore, we rely and plan to continue to rely on strategic alliances to financially help us develop and commercialize certain of our drug candidates. As a result, our success depends, in part, on our ability to collect milestone and royalty payments from our existing collaborators, AstraZeneca, Eli Lilly, Nestlé Health Science and potential new collaborators. To the extent our collaborators do not aggressively pursue drug candidates for which we are entitled to such payments or pursue such drug candidates ineffectively, we will fail to realize these significant revenue streams, which could have an adverse effect on our business and future prospects.

If the alliances we currently have with AstraZeneca, Eli Lilly and Nestlé Health Science, or future collaborators with whom we may engage, are unable or unwilling to advance our programs, or if they do not diligently pursue product development and product approval, this may slow our progress and defer our revenue. Any such failure would have an adverse effect on our ability to collect key revenue streams and, for this reason, would adversely impact our business, financial position and prospects. Our collaborators may sub-license or abandon drug candidates or we may have disagreements with our collaborators, which would cause associated product development to slow or cease. There can be no assurance that our current strategic alliances will be successful, and we may require significant time to secure new strategic alliances because we need to effectively market the benefits of our technology to these future alliance partners, which may direct the attention and resources of our research and development personnel and management away from our primary business operations. Further, each strategic alliance arrangement will involve the negotiation of terms that may be unique to each collaborator. These business development efforts may not result in a strategic alliance or may result in unfavorable arrangements.

Under typical collaboration agreements, we would expect to receive revenue for our selective kinase inhibitors based on achievement of specific development, sales or regulatory approval milestones, as well as royalties based on a percentage of sales of the commercialized products. Achieving these milestones will depend, in part, on the efforts of our partner as well as our own. If we, or any alliance partner, fail to meet specific milestones, then the strategic alliance may be terminated, which could reduce our revenue.

The third-party vendors upon whom we rely for the supply of the active pharmaceutical ingredient, drug product and drug substance used in our drug candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients, or API, drug product and drug substance used in our drug candidates are supplied to us from third-party vendors. Our ability to successfully develop our drug candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. While we do produce small amounts of API, we do not currently have arrangements in place for a redundant or second-source supply of any such API, drug product or drug substance in the event any of our current suppliers of such API, drug product and drug substance cease their operations for any reason, which may lead to an interruption in our production.

For all of our drug candidates, we intend to identify and qualify additional manufacturers to provide such API, drug product and drug substance prior to submission of an NDA to the FDA and/or CFDA. We are not certain, however, that our current suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and drug substance used in our drug candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug product and drug substance used in our drug candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We and our collaborators rely, and expect to continue to rely, on third parties to conduct certain of our clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be harmed.

We do not have the ability to independently conduct large-scale clinical trials. We and our collaboration partners rely, and expect to continue to rely, on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support certain clinical trials for our drug candidates. Nevertheless, we and our collaboration partners (as applicable) will be responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of clinical trials for our drug candidates, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

Although we or our collaboration partners design the clinical trials for our drug candidates, CROs conduct most of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct clinical trials results in less control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- · undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially and adversely affect the willingness or ability of third parties to conduct our and our collaboration partners' clinical trials and may subject us or them to unexpected cost increases that are beyond our or their control.

If any of our and our collaboration partners' relationships with these third-party CROs terminate, we or they may not be able to enter into arrangements with alternative CROs on reasonable terms or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, we believe that our financial results and the commercial prospects for our drug candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

# We, our collaboration partners or our CROs may fail to comply with the regulatory requirements pertaining to clinical trials, which could result in fines, adverse publicity and civil or criminal sanctions.

We, our collaboration partners and our CROs are required to comply with regulations for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the CFDA and comparable foreign regulatory authorities for any drugs in clinical development. In the United States, the FDA regulates GCP through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our collaboration partners or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require additional clinical trials before approving the marketing applications for the relevant drug candidate. We cannot assure you that, upon inspection, the FDA or other applicable regulatory authority will determine that any of the future clinical trials for our drug candidates will comply with GCPs. In addition, clinical trials must be conducted with drug candidates produced under applicable GMP regulations. Our failure or the failure of our collaboration partners or CROs to comply with these regulations may require us or them to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We are also required to register applicable clinical trials and post certain results of completed clinical trials on a governmentsponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil sanctions.

### Joint ventures form an important part of our Commercial Platform business, and our ability to manage and develop the businesses conducted by these joint ventures depends in part on our relationship with our joint venture partners.

We are party to joint venture agreements with each of Shanghai Pharmaceuticals, Guangzhou Baiyunshan, Sinopharm and Hain Celestial, which together form an important part of our Commercial Platform business. Under these arrangements, our joint venture partners have certain operational responsibilities and/or certain rights to exercise control or influence over operations and decision-making.

Our equity interests in these operating companies do not provide us with the ability to control actions which require shareholder approval. In addition, under the joint venture contracts for these entities, the consent of the directors nominated by our joint venture partners is required for the passing of resolutions in relation to certain matters concerning the operations of these companies. As a result, although we participate in the management, and in the case of Sinopharm and Shanghai Pharmaceuticals nominate the management and run the day-to-day operations, we may not be able to secure the consent of our joint venture partners to pursue activities or strategic objectives that are beneficial to or that facilitate our overall business strategies. With respect to Hutchison Baiyunshan, which is a jointly controlled and managed joint venture where we share the ability to appoint the general manager with our partner Guangzhou Baiyunshan, with each of us having a rotating four-year right, we rely on our relationship with our partner, and our ability to manage the day-to-day operations of this joint venture is more limited. To the extent Guangzhou Baiyunshan does not, for example, diligently perform its responsibilities with respect to any aspect of Hutchison Baiyunshan's operations, agree with or cooperate in the implementation of any plans we may have for Hutchison Baiyunshan's business in the future or take steps to ensure that Hutchison Baiyunshan is in compliance with applicable laws and regulations, our business and ability to comply with legal, regulatory and financial reporting requirements which will apply to us as a public company, as well as the results of this joint venture, could be materially and adversely affected. Furthermore, disagreements or disputes which arise between us and our joint venture partners may potentially require legal action to resolve and hinder the smooth operation of our Commercial Platform business or adversely affect our financial condition, results of operations and prospects.

### We and our joint ventures rely on our distributors for logistics and distribution services for our Commercial Platform business.

We and our joint ventures rely on distributors to perform certain operational activities, including invoicing, logistics and delivery of the products we and they market to the end customers. Because we and our joint ventures rely on third-party distributors, we have less control than if we handled distribution logistics directly and can be adversely impacted by the actions of our distributors. Any disruption of our distribution network, including failure to renew existing distribution agreements with desired distributors, could negatively affect our ability to effectively sell our products and materially and adversely affect the business, financial condition and results of operations of us and our joint ventures.

### There is no assurance that the benefits currently enjoyed by virtue of our association with CK Hutchison will continue to be available.

Historically, we have relied on the reputation and experience of, and support provided by, our founding shareholder, Hutchison Whampoa Limited (a wholly owned subsidiary of CK Hutchison), to advance our joint ventures and collaborations in China and elsewhere. CK Hutchison is a Hong Kong-based, multinational conglomerate with operations in over 50 countries. CK Hutchison is the ultimate parent company of Hutchison Healthcare Holdings Limited, which as of March 1, 2018, owns 60.4% of our total outstanding share capital. We believe that CK Hutchison group's reputation in China has given us an advantage in negotiating collaborations and obtaining opportunities.

We also benefit from sharing certain services with the CK Hutchison group including, among others, legal and regulatory services, company secretarial support services, tax and internal audit services, shared

use of accounting software system and related services, participation in the CK Hutchison group's pension, medical and insurance plans, participation in the CK Hutchison group's procurement projects with third-party vendors/suppliers, other staff benefits and staff training services, company functions and activities and operation advisory and support services. We pay a management fee to an affiliate of CK Hutchison for the provision of such services. In the years ended December 31, 2015, 2016 and 2017, we paid a management fee of approximately \$845,000, \$874,000 and \$897,000, respectively. In addition, we benefit from the fact that two retail chains affiliated with the CK Hutchison group, PARKnSHOP and Watsons, sell certain of our Commercial Platform products in their stores throughout Hong Kong and in other Asian countries. For the years ended December 31, 2015, 2016 and 2017, sales of our products to members of the CK Hutchison group amounted to \$8.1 million, \$9.8 million and \$8.5 million, respectively.

Our business also depends on certain intellectual property rights licensed to us by the CK Hutchison group. See "—Risks Related to Intellectual Property—We and our joint ventures are dependent on trademark and other intellectual property rights licensed from others. If we lose our licenses for any of our products, we or our joint ventures may not be able to continue developing such products or may be required to change the way we market such products" for more information on risks associated with such intellectual property licensed to us.

There can be no assurance the CK Hutchison group will continue to provide the same benefits or support that they have provided to our business historically. Such benefit or support may no longer be available to us, in particular, if CK Hutchison's ownership interest in our company significantly decreases in the future.

#### Other Risks and Risks Related to Doing Business in China

We and our joint ventures may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, the Bribery Act 2010 of the Parliament of the United Kingdom, or U.K. Bribery Act, and Chinese anti-corruption laws, and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

In the day-to-day conduct of our business, we and our joint ventures are in frequent contact with persons who may be considered government officials under applicable anti-corruption, anti-bribery and anti-kickback laws, and therefore, we and our joint ventures are subject to risk of violations under the FCPA, the U.K. Bribery Act, and other laws in the countries where we do business. We and our joint ventures have operations, agreements with third parties and we and our joint ventures make most of our sales in China. The PRC also strictly prohibits bribery of government officials. Our and our joint ventures' activities in China create the risk of unauthorized payments or offers of payments by the directors, employees, representatives, distributors, consultants or agents of our company or our joint ventures, even though they may not always be subject to our control.

It is our policy to implement safeguards to discourage these practices by our and our joint ventures' employees. We have implemented and adopted policies designed by the R&D-based Pharmaceutical Association Committee, an industry association representing 40 global biopharmaceutical companies, to ensure compliance by us and our joint ventures and our and their directors, officers, employees, representatives, distributors, consultants and agents with the anti-corruption laws and regulations. We cannot assure you, however, that our existing safeguards are sufficient or that our or our joint ventures' directors, officers, employees, representatives, distributors, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, the U.K. Bribery Act or Chinese anti-corruption laws may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, reputation financial condition, cash flows and results of operations.

Ensuring that our and our joint ventures' future business arrangements with third parties comply with applicable laws could also involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our or our joint ventures' operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment and exclusion from government funded healthcare programs, any of which could substantially disrupt our operations. If the physicians, hospitals or other providers or entities with whom we and our joint ventures do business are found not to be in compliance with applicable laws, they may also be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

If we or our joint ventures fail to comply with environmental, health and safety laws and regulations, we or they could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our joint ventures are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemical materials. Our operations also produce hazardous waste products. We and our joint ventures are therefore subject to PRC laws and regulations concerning the discharge of waste water, gaseous waste and solid waste during our manufacturing processes. We and our joint ventures are required to establish and maintain facilities to dispose of waste and report the volume of waste to the relevant government authorities, which conduct scheduled or unscheduled inspections of our facilities and treatment of such discharge. We and our joint ventures may not at all times comply fully with environmental regulations. Any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our facilities and obligation to take corrective measures. We and our joint ventures generally contract with third parties for the disposal of these materials and waste. We and our joint ventures cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from the use of hazardous materials, we and/or our joint ventures could be held liable for any resulting damages, and any liability could exceed our resources. We and/or our joint ventures also could incur significant costs associated with civil or criminal fines and penalties.

Although we and our joint ventures maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees and third-party liability insurance for injuries caused by unexpected seepage, pollution or contamination, this insurance may not provide adequate coverage against potential liabilities. Furthermore, the PRC government may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, we and our joint ventures may need to incur substantial capital expenditures to install, replace, upgrade or supplement our equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our or our joint ventures' business operations.

#### Product liability claims or lawsuits could cause us or our joint ventures to incur substantial liabilities.

We and our joint ventures face an inherent risk of product liability exposure related to the use of our drug candidates in clinical trials, sales of our or our joint ventures' products or the products we or they license from third parties through our Commercial Platform. If we and our joint ventures cannot

successfully defend against claims that the use of such drug candidates in our clinical trials or any products sold through our Commercial Platform, including any of our drug candidates which receive regulatory approval, caused injuries, we and our joint ventures could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any products sold through our Commercial Platform;
- significant negative media attention and reputational damage;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- · loss of revenue; and
- the inability to commercialize any drug candidates that we may develop.

Existing PRC laws and regulations do not require us or our joint ventures to have, nor do we or they, maintain liability insurance to cover product liability claims. We and our joint ventures do not have business liability, or in particular, product liability for each of our drug candidates or certain of our or their products. Any litigation might result in substantial costs and diversion of resources. While we and our joint ventures maintain liability insurance for certain clinical trials, this insurance may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop.

## We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We are heavily dependent on critical, complex and interdependent information technology systems, including internet-based systems, to support our business processes. Our information technology system security is continuously reviewed, maintained and upgraded in response to possible security breach incidents. Despite the implementation of these measures, our information technology systems and those of third parties with which we contract are vulnerable to damage from external or internal security incidents, breakdowns, malicious intrusions, cybercrimes, including State-sponsored cybercrimes, malware, misplaced or lost data, programming or human errors or other similar events. System failures, accidents or security breaches could cause interruptions in our operations and could result in inappropriately accessed, tampered with, modified or stolen scientific data or a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. Such event could significantly harm our Innovation Platform's operations, including resulting in the loss of clinical trial data which could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Such events could also lead to the loss of important information such as trade secrets or other intellectual property and could accelerate the development or manufacturing of competing products by third parties. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs and the development of our drug candidates could be delayed.

## The PRC's economic, political and social conditions, as well as governmental policies, could affect the business environment and financial markets in China, our ability to operate our business, our liquidity and our access to capital.

Substantially all of our and our joint ventures' business operations are conducted in China. Accordingly, our results of operations, financial condition and prospects are subject to a significant degree

to economic, political and legal developments in China. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth in the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures benefit the overall PRC economy, but may have a negative effect on us or our joint ventures. 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 or our joint ventures. More generally, if the business environment in China deteriorates from the perspective of domestic or international investors, our or our joint ventures' business in China may also be adversely affected.

## Uncertainties with respect to the PRC legal system and changes in laws, regulations and policies in China could materially and adversely affect us.

We conduct our business primarily through our subsidiaries and joint ventures in China. PRC laws and regulations govern our and their operations in China. Our subsidiaries and joint ventures are generally subject to laws and regulations applicable to foreign investments in China, which may not sufficiently cover all of the aspects of our or their economic activities in China. In particular, some laws, particularly with respect to drug price reimbursement, are relatively new, and because of the limited volume of published judicial decisions and their non-binding nature, the interpretation and enforcement of these laws and regulations are uncertain. Furthermore, recent regulatory reform in the China pharmaceutical industry will limit the number of distributors allowed between a manufacturer and each hospital to one, which may limit the rate of sales growth of Hutchison Sinopharm in future periods. In addition, the implementation of laws and regulations may be in part based on government policies and internal rules that are subject to the interpretation and discretion of different government agencies (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not be aware of our, our collaboration partners' or our joint ventures' violation of these policies and rules until sometime after the violation. In addition, any litigation in China, regardless of outcome, may be protracted and result in substantial costs and diversion of resources and management attention.

For further information regarding government regulation in China and other jurisdictions, see Item 4.B. "Business Overview—Regulation—Government Regulation of Pharmaceutical Product Development and Approval—PRC Regulation of Pharmaceutical Product Development and Approval," "Business Overview—Regulation—Coverage and Reimbursement—PRC Coverage and Reimbursement" and "Business Overview—Regulation—Other Healthcare Laws—Other PRC Healthcare Laws."

#### Restrictions on currency exchange may limit our ability to receive and use our revenue effectively.

Substantially all of our revenue is denominated in renminbi, which currently is not a freely convertible currency. A portion of our revenue may be converted into other currencies to meet our foreign currency obligations, including, among others, payments of dividends declared, if any, in respect of our ordinary shares or ADSs. Under China's existing foreign exchange regulations, our subsidiaries and joint ventures are able to pay dividends in foreign currencies or convert renminbi into other currencies for use in operations without prior approval from the PRC State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. However, we cannot assure you that the PRC government will not take future measures to restrict access to foreign currencies for current account transactions.

Our PRC subsidiaries' and joint ventures' ability to obtain foreign exchange is subject to significant foreign exchange controls and, in the case of amounts under the capital account, requires the approval of and/or registration with PRC government authorities, including the SAFE. In particular, if we finance our PRC subsidiaries or joint ventures by means of foreign debt from us or other foreign lenders, the amount is

not allowed to exceed either the cross-border financing risk weighted balance calculated based on a formula by the PBOC or the difference between the amount of total investment and the amount of the registered capital as acknowledged by the Ministry of Commerce, or MOFCOM, and the SAFE. Further, such loans must be filed with and registered with the SAFE or their local branches and the National Development and Reform Commission (if applicable). If we finance our PRC subsidiaries or joint ventures by means of additional capital contributions, the amount of these capital contributions must first be filed with the relevant government approval authority. These limitations could affect the ability of our PRC subsidiaries and joint ventures to obtain foreign exchange through debt or equity financing.

Our business benefits from certain PRC government tax incentives. The expiration of, changes to, or our PRC subsidiaries/joint ventures failing to continuously meet the criteria for these incentives could have a material adverse effect on our operating results by significantly increasing our tax expenses.

Certain of our PRC subsidiaries and joint ventures have been successful in their respective applications to renew the special High and New Technology Enterprise, or HNTE, status (since 2005, 2008 or 2014) and/or granted the Technological Advance Service Enterprise, or TASE, status (since 2010) by the relevant PRC authorities. Both of these statuses allow the relevant enterprise to enjoy a reduced Enterprise Income Tax, or EIT, rate at 15% on its taxable profits. The statuses are valid until the end of 2019 (for HNTE, renewal is done every three years) or 2018 (for TASE, renewal is done every three years in general) during which the relevant PRC enterprise must continue to meet the relevant criteria or else the 25% standard EIT rate will be applied from the beginning of the calendar year when the enterprise fails to meet the relevant criteria. In addition, it is unclear whether the HNTE/TASE status and tax incentives under the current policy will continue to be granted after their respective expiration dates. If the rules for such incentives are amended or the statutes are not renewed, higher EIT rates may apply resulting in increased tax burden which will impact our business, financial condition, results of operations and growth prospects.

## We may be treated as a resident enterprise for PRC Tax purposes under the PRC EIT Law, and our global income may therefore be subject to PRC income tax.

China's EIT Law and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008, define the term "de facto management bodies" as "bodies that substantially carry out comprehensive management and control on the business operation, employees, accounts and assets of enterprises." Under the EIT Law, an enterprise incorporated outside of China whose "de facto management bodies" are located in China is considered a "resident enterprise" and will be subject to a uniform 25% EIT rate on its global income. On April 22, 2009, China's State Administration of Taxation, or the SAT, in the Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, further specified certain criteria for the determination of what constitutes "de facto management bodies." If all of these criteria are met, the relevant foreign enterprise may be regarded to have its "de facto management bodies" located in China and therefore be considered a resident enterprise in China. These criteria include: (i) the enterprise's day-to-day operational management is primarily exercised in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or subject to approval by organizations or personnel in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholders' meeting minutes are located or maintained in China; and (iv) 50% or more of voting board members or senior executives of the enterprise habitually reside in China. Although Circular 82 only applies to foreign enterprises that are majority-owned and controlled by PRC enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in Circular 82 may be adopted by the PRC tax authorities as the test for determining whether the enterprises are PRC tax residents, regardless of whether they are majority-owned and controlled by PRC enterprises.

Except for our PRC subsidiaries and joint ventures incorporated in China, we believe that none of our entities incorporated outside of China is a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities, and uncertainties remain with respect to the interpretation of the term "de facto management body."

If we are treated as a PRC tax resident, dividends distributed by us to our non-PRC shareholders and ADS holders or any gains realized by non-PRC shareholders and ADS holders from the transfer of our shares or ADSs may be subject to PRC tax.

Under the EIT Law, dividends payable by a PRC enterprise to its foreign investor who is a non-PRC resident enterprise, as well as gains on transfers of shares of a PRC enterprise by such a foreign investor will generally be subject to a 10% withholding tax, unless such non-PRC resident enterprise's jurisdiction of tax residency has an applicable tax treaty with the PRC that provides for a reduced rate of withholding tax.

If the PRC tax authorities determine that we should be considered a PRC resident enterprise for EIT purposes, any dividends payable by us to our non-PRC resident enterprise shareholders or ADS holders, as well as gains realized by such investors from the transfer of our shares or ADSs may be subject to a 10% withholding tax, unless a reduced rate is available under an applicable tax treaty. Furthermore, if we are considered a PRC resident enterprise for EIT purposes, it is unclear whether our non-PRC individual shareholders (including our ADS holders) would be subject to any PRC tax on dividends or gains obtained by such non-PRC individual shareholders. If any PRC tax were to apply to dividends or gains realized by non-PRC individuals, it would generally apply at a rate of up to 20% unless a reduced rate is available under an applicable tax treaty. If dividends payable to our non-PRC resident shareholders, or gains from the transfer of our shares or ADSs by such shareholders are subject to PRC tax, the value of your investment in our shares or ADSs may decline significantly.

There is uncertainty regarding the PRC withholding tax rate that will be applied to distributions from our PRC subsidiaries and joint ventures to their respective Hong Kong immediate holding companies, which could have a negative impact on our business.

The EIT Law provides that a withholding tax at the rate of 10% is applicable to dividends payable by a PRC resident enterprise to investors who are "non-resident enterprises" (i.e., that do not have an establishment or place of business in the PRC or that have such establishment or place of business but the relevant dividend is not effectively connected with the establishment or place of business). However, pursuant to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income, or the Arrangement, withholding tax at a reduced rate of 5% may be applicable to dividends payable by PRC resident enterprises to beneficial owners of the dividends that are Hong Kong tax residents if certain requirements are met.

There is uncertainty regarding whether the PRC tax authorities will consider us to be eligible to the reduced tax rate. If the Arrangement is deemed not to apply to dividends payable by our PRC subsidiaries and joint ventures to their respective Hong Kong immediate holding companies that are ultimately owned by us, the withholding tax rate applicable to us will be the statutory rate of 10% instead of 5% which may potentially impact our business, financial condition, results of operations and growth prospects.

We may be treated as a resident enterprise for U.K. corporate tax purposes, and our global income may therefore be subject to U.K. corporation tax.

U.K. resident companies are taxable in the United Kingdom on their worldwide profits. A company incorporated outside of the United Kingdom would be regarded as a resident if its central management and control resides in the United Kingdom. The place of central management and control generally means the place where the high-level strategic decisions of a company are made.

We are an investment holding company incorporated in the Cayman Islands that is listed on the AIM market of the London Stock Exchange. Our central management and control resides in Hong Kong, and therefore we believe that we are not a U.K. resident for corporate tax purposes. However, the tax resident status of a non-resident entity could be challenged by the U.K. tax authorities.

If the U.K. tax authorities determine that we are a U.K. tax resident, our profits will be subject to U.K. Corporation Tax rate at 19.25%, subject to the potential availability of certain exemptions related to dividend income and capital gains. This may have a material adverse effect on our financial condition and results of operations.

Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies. Based on this regulation, PRC residents who are granted shares or share options by a company listed on an overseas stock market under its employee share option or share incentive plan are required to register with the SAFE or its local counterparts by following certain procedures. We and our employees who are PRC residents and individual beneficial owners who have been granted shares or share options have been subject to these rules due to our listing on the AIM market of the London Stock Exchange and the listing of our ADSs on the Nasdaq Global Select Market. We have registered the option schemes and the share incentive plan and will continue to assist our employees to register their share options or shares. However, any failure of our PRC individual beneficial owners and holders of share options or shares to comply with the SAFE registration requirements in the future may subject them to fines and legal sanctions and may, in rare instances, limit the ability of our PRC subsidiaries to distribute dividends to us.

In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax, or IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. Although the PRC subsidiaries currently withhold IIT from the PRC employees in connection with their exercise of share options, if they fail to report and pay the tax withheld according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

#### Risks Related to Intellectual Property

If we, our joint ventures or our collaboration partners are unable to protect our or their products and drug candidates through intellectual property rights, our competitors may compete directly against us or them.

Our success depends, in part, on our, our joint venture partners' and our collaboration partners' ability to protect our and our joint ventures' and our collaboration partners' products and drug candidates from competition by establishing, maintaining and enforcing our or their intellectual property rights. We, our joint ventures and our collaboration partners seek to protect the products and technology that we and they consider commercially important by filing PRC and international patent applications, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. As of December 31, 2017, we had 151 issued patents, including 18 Chinese patents, 19 U.S. patents and eight European patents, 146 patent applications pending in the above major market jurisdictions, and two pending Patent Cooperation Treaty, or PCT, patent applications relating to the drug candidates of our Innovation Platform. Our collaboration partner AstraZeneca is responsible for maintaining and enforcing our intellectual property rights in relation to savolitinib. As of the same date, our joint venture Nutrition Science Partners had 24 issued patents and three pending patent applications relating to HMPL-004 and its reformulation HM004-6599. Additionally, our joint ventures collectively had 119 issued patents and 10 patent applications in China and other jurisdictions relating to our Commercial Platform's products as of December 31, 2017. For more details, see Item 4.B. "Business Overview—Patents and Other Intellectual Property." Patents may become invalid and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of originality of the technology. In addition, the PRC and the United States have adopted the "first-to-file" system under which whoever first files an invention patent application will be awarded the patent. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented. Furthermore, the terms of patents are finite. The patents we hold and patents to be issued from our currently pending patent applications generally have a twenty-year protection period starting from the date of application.

We, our joint ventures and/or our collaboration partners may become involved in patent litigation against third parties to enforce our or their patent rights, to invalidate patents held by such third parties, or to defend against such claims. A court may refuse to stop the other party from using the technology at issue on the grounds that our or our joint ventures' patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we or our joint ventures infringe their intellectual property or that a patent we, our joint ventures or our collaboration partners have asserted against them is invalid or unenforceable. In patent litigation, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us or our intellectual property to assert such challenges to our intellectual property rights.

The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information or made a misleading statement during prosecution. It is possible that prior art of which we, our joint ventures or our collaboration partners and the patent examiner were unaware during prosecution exists, which could render our or their patents invalid. Moreover, it is also possible that prior art may exist that we, our joint ventures or our collaboration partners are aware of but do not believe is relevant to our or their current or future patents, but that could nevertheless be determined to render our patents invalid. The cost to us or our joint ventures of any patent litigation or similar proceeding could be substantial, and it may consume significant management time. We and our joint ventures do not maintain insurance to cover intellectual property infringement.

An adverse result in any litigation proceeding could put one or more of our or our joint ventures' patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our or our joint ventures' products or our drug candidates, we could lose at least part, and perhaps all, of the patent protection covering such product or drug candidate. Competing drugs may also be sold in other countries in which our or our joint ventures' patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our or our joint ventures' infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business.

Intellectual property and confidentiality legal regimes in China may not afford protection to the same extent as in the United States or other countries. Implementation and enforcement of PRC intellectual property laws may be deficient and ineffective. Policing unauthorized use of proprietary technology is difficult and expensive, and we or our joint ventures may need to resort to litigation to enforce or defend patents issued to us or them or to determine the enforceability, scope and validity of our proprietary rights or those of others. The experience and capabilities of PRC courts in handling intellectual property litigation varies, and outcomes are unpredictable. Further, such litigation may require a significant expenditure of cash and may divert management's attention from our or our joint ventures' operations, which could harm our business, financial condition and results of operations. An adverse determination in any such litigation could materially impair our or our joint ventures' intellectual property rights and may harm our business, prospects and reputation.

#### Developments in patent law could have a negative impact on our business.

From time to time, authorities in the United States, China and other government authorities may change the standards of patentability, and any such changes could have a negative impact on our business.

For example, in the United States, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. As a result of these changes, patent law in the United States may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The U.S. Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our or our joint ventures' patent applications and our or their ability to obtain patents based on our or our joint ventures' discoveries and to enforce or defend any patents that may issue from our or their patent applications, all of which could have a material adverse effect on our business.

## If we are unable to maintain the confidentiality of our and our joint ventures' trade secrets, the business and competitive position of ourselves and our joint ventures may be harmed.

In addition to the protection afforded by patents and the PRC's State Secret certification, we and our joint ventures rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our and our joint ventures' proprietary technology and processes, in part, by entering into confidentiality agreements with our and their collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our and their consultants and employees. We and our joint ventures may not be able to prevent the unauthorized disclosure or use of our or their technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we and our joint ventures may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third-party illegally obtained and is using our or our joint ventures' trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts in China and other jurisdictions outside the United States are sometimes less prepared or willing to protect trade secrets.

Our and our joint ventures' trade secrets could otherwise become known or be independently discovered by our or their competitors. For example, competitors could purchase our drugs and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our or our joint ventures' trade secrets were to be lawfully obtained or independently developed by a competitor, we and our joint ventures would have no right to prevent them, or others to whom they communicate it, from using that technology or information to compete against us or our joint ventures. If our or our joint ventures' trade secrets are unable to adequately protect our business against competitors' drugs, our competitive position could be adversely affected, as could our business.

We and our joint ventures are dependent on trademark and other intellectual property rights licensed from others. If we lose our licenses for any of our products, we or our joint ventures may not be able to continue developing such products or may be required to change the way we market such products.

We and our joint ventures are parties to licenses that give us or them rights to third-party intellectual property that are necessary or useful for our or our joint ventures' businesses. In particular, the "Hutchison," "Chi-Med" and "China-MediTech" brands, among others, have been licensed to us by Hutchison Whampoa Enterprises Limited, an affiliate of our majority shareholder, Hutchison Healthcare Holdings Limited. Hutchison Whampoa Enterprises Limited grants us a royalty-free, worldwide license to such brands. Hutchison Whampoa Enterprises Limited has the right to terminate the license during the 12-month period following each time the interest of Hutchison Whampoa Limited, an indirect shareholder of Hutchison Healthcare Holdings Limited, in us is reduced below 50%, 40%, 30% or 20%. Currently, Hutchison Whampoa Limited's interest in our company is less than 20%, but we do not anticipate that Hutchison Whampoa Enterprises Limited will terminate such license in the foreseeable future. In addition, the "Baiyunshan" brand, which is a key brand used by Hutchison Baiyunshan on its products, has been licensed to Hutchison Baiyunshan by our joint venture partner, Guangzhou Baiyunshan, for use during the 50-year joint venture period; however, Guangzhou Baiyunshan has the right to terminate the license if its interest in Hutchison Baiyunshan falls below 50%. If any such license is terminated, our or Hutchison Baiyunshan's business, and our or their positioning in the Chinese market and our financial condition, results of operations and prospects may be materially and adversely affected.

In some cases, our licensors have retained the right to prosecute and defend the intellectual property rights licensed to us or our joint ventures. We depend in part on the ability of our licensors to obtain, maintain and enforce intellectual property protection for such licensed intellectual property. Such licensors may not successfully maintain their intellectual property, may determine not to pursue litigation against other companies that are infringing on such intellectual property, or may pursue litigation less aggressively than we or our joint ventures would. Without protection for the intellectual property we or our joint ventures license, other companies might be able to offer substantially identical products or branding, which could adversely affect our competitive business position and harm our business prospects.

If our or our joint ventures' products or drug candidates infringe the intellectual property rights of third parties, we and they may incur substantial liabilities, and we and they may be unable to sell these products.

Our commercial success depends significantly on our and our joint ventures' ability to operate without infringing the patents and other proprietary rights of third parties. In the PRC, invention patent applications are generally maintained in confidence until their publication 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and invention patent applications are filed. Even after reasonable investigation, we may not know with certainty whether any third-party may have filed a patent application without our knowledge while we or our joint ventures are still developing or producing that product. While the success of pending patent applications and applicability of any of them to our or our joint ventures' programs are uncertain, if asserted against us or them, we could incur substantial costs and we or they may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- · redesign products or processes to avoid infringement; and
- stop producing products using the patents held by others, which could cause us or them to lose the use of one or more of our or their products.

To date, we and our joint ventures have not received any material claims of infringement by any third parties. If a third-party claims that we or our joint ventures infringe its proprietary rights, any of the following may occur:

- we or our joint ventures may have to defend litigation or administrative proceedings that may be costly whether we or they win or lose, and which could result in a substantial diversion of management resources;
- we or our joint ventures may become liable for substantial damages for past infringement if a court decides that our technology infringes a third-party's intellectual property rights;
- a court may prohibit us or our joint ventures from producing and selling our or their product(s) without a license from the holder of the intellectual property rights, which may not be available on commercially acceptable terms, if at all; and
- we or our joint ventures may have to reformulate product(s) so that it does not infringe the intellectual property rights of others, which may not be possible or could be very expensive and time consuming.

Any costs incurred in connection with such events or the inability to sell our or our joint ventures' products may have a material adverse effect on our business and results of operations.

## We, our joint ventures and our collaboration partners may not be able to effectively enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our or our joint venture's products or drug candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our, our joint ventures' or our collaboration partners' ability to protect and enforce our or their intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, the patent laws of some foreign countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, may not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us or our joint ventures to stop the infringement of our or their patents or the misappropriation of our or their other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our or our joint ventures' inventions throughout the world. Competitors may use our or our joint ventures' technologies in jurisdictions where we or they have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to territories where we or our joint ventures have patent protection, if our, our joint ventures' or our collaboration partners' ability to enforce our or their patents to stop infringing activities is inadequate. These drugs may compete with our drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our or our joint ventures' patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our or their efforts and resources from other aspects of our and their businesses. While we intend to protect our intellectual property rights in the major markets for our drug candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our drug candidates. Furthermore, as AstraZeneca is responsible for enforcing our intellectual property rights with respect to savolitinib on our behalf, we may be unable to ensure that such rights are enforced or maintained in all jurisdictions. Accordingly, our efforts to protect the intellectual property rights of our drug candidates in such countries may be inadequate.

We and our joint ventures may be subject to damages resulting from claims that we or they, or our or their employees, have wrongfully used or disclosed alleged trade secrets of competitors or are in breach of non-competition or non-solicitation agreements with competitors.

We and our joint ventures could in the future be subject to claims that we or they, or our or their employees, have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our and our joint ventures' employees and consultants do not improperly use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us or our joint ventures, we or our joint ventures may in the future be subject to claims that we or they caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we, our joint ventures, or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we and our joint ventures are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our or our joint ventures' defenses to these claims fail, in addition to requiring us and them to pay monetary damages, a court could prohibit us or our joint ventures from using technologies or features that are essential to our or their products or our drug candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing our drug candidates. In addition, we or our joint ventures may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our or our joint ventures' ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates, which would have an adverse effect on our business, results of operations and financial condition.

#### Risks Related to Our ADSs

Certain shareholders own a significant percentage of our ordinary shares, which limits the ability of other shareholders to influence corporate matters.

As of March 1, 2018, Hutchison Healthcare Holdings Limited owns approximately 60.4% of our ordinary shares. Accordingly, Hutchison Healthcare Holdings Limited has a significant influence over the outcome of any corporate transaction or other matter submitted to shareholders for approval and the interests of Hutchison Healthcare Holdings Limited may differ from the interests of our other shareholders. Because we are incorporated in the Cayman Islands, certain matters, such as amendments to our memorandum and articles of association, require approval of at least two-thirds of our shareholders by law subject to higher thresholds which we may set in our memorandum and articles of association. Therefore, Hutchison Healthcare Holdings Limited's approval will be required to achieve any such threshold. In addition, Hutchison Healthcare Holdings Limited will have a significant influence over the management and the strategic direction of our company.

Substantial future sales or perceived potential sales of our ADSs, ordinary shares or other equity or equity-linked securities in the public market could cause the price of our ADSs to decline significantly.

Sales of our ADSs, ordinary shares or other equity or equity-linked securities in the public market, or the perception that these sales could occur, could cause the market price of our ADSs to decline significantly. All of our ordinary shares represented by ADSs are freely transferable by persons other than our affiliates without restriction or additional registration under the Securities Act of 1933, or the Securities Act. The ordinary shares held by our affiliates are also available for sale, subject to volume and other restrictions as applicable under Rules 144 and 701 under the Securities Act, under sales plans adopted pursuant to Rule 10b5-1 or otherwise.

We have filed with the SEC a Registration Statement on Form F-3, commonly referred to as a "shelf registration," that permits us to sell any number of ADSs in a registered offering at our discretion. The shelf registration was automatically effective as of the filing date, April 3, 2017. On October 30, 2017, we completed a registered offering of 11,369,810 ADSs under the shelf registration statement, raising total gross proceeds of approximately \$301.3 million. We may decide to conduct future offerings from time to time, and such sales could cause the price of our ADSs to decline significantly.

#### We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

## If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our business, the price of our ADSs could decline.

The trading market for our ADSs will rely in part on the research and reports that industry or financial analysts publish about us or our business. We may never obtain research coverage by industry or financial analysts. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

## As a foreign private issuer, we are not subject to certain U.S. securities law disclosure requirements that apply to a domestic U.S. issuer, which may limit the information publicly available to our shareholders.

As a foreign private issuer we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act and therefore there may be less publicly available information about us than if we were a U.S. domestic issuer. For example, we are not subject to the proxy rules in the United States and disclosure with respect to our annual general meetings will be governed by the AIM Rules for Companies, or the AIM Rules, and Cayman Islands requirements. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules thereunder. Therefore, our shareholders may not know on a timely basis when our officers, directors and principal shareholders purchase or sell our ordinary shares or ADSs.

# As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer, we are permitted to take advantage of certain provisions in the Nasdaq listing rules that allow us to follow Cayman Islands law for certain governance matters. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards as, except for general fiduciary duties and duties of care, Cayman Islands law has no corporate governance regime which prescribes specific corporate governance standards. We intend to continue to follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Global Select Market in respect of the following: (i) the majority independent director requirement under Section 5605(b)(1) of the Nasdaq listing rules, (ii) the requirement under Section 5605(d) of the Nasdaq listing rules that a remuneration committee comprised solely of independent directors governed by a remuneration committee charter oversee executive compensation and (iii) the requirement under Section 5605(e) of the Nasdaq listing rules that director nominees be selected

or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors. Cayman Islands law does not impose a requirement that our board of directors consist of a majority of independent directors. Nor does Cayman Islands law impose specific requirements on the establishment of a remuneration committee or nominating committee or nominating process. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers. We have voluntarily complied with, and plan to continue to comply with for the foreseeable future, the principles of the U.K. Corporate Governance Code published by the U.K. Financial Reporting Council which guides certain of our other corporate governance practices. See Item 6.C. "Board Practice—U.K. Corporate Governance Code" for more details.

## We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As discussed above, we are a foreign private issuer, and therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act. The determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to us on June 30, 2018. We would lose our foreign private issuer status if, for example, more than 50% of our ordinary shares are directly or indirectly held by residents of the United States on June 30, 2018 and we fail to meet additional requirements necessary to maintain our foreign private issuer status. If we lose our foreign private issuer status on this date, we will be required to file with the SEC periodic reports and registration statements on U.S. domestic issuer forms beginning on January 1, 2019, which are more detailed and extensive than the forms available to a foreign private issuer. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements under the Nasdaq listing rules. As a U.S.-listed public company that is not a foreign private issuer, we will incur significant additional legal, accounting and other expenses that we will not incur as a foreign private issuer.

## Certain audit reports included in this annual report were prepared by an auditor who is not inspected by the U.S. Public Company Accounting Oversight Board, or the PCAOB, and as such, you are deprived of the benefits of such inspection.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including the independent registered public accounting firm of our company, must be registered with the PCAOB, and are required by the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Because we have substantial operations within the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese authorities, our auditor and the auditors of our joint ventures are not currently inspected by the PCAOB.

In May 2013, the PCAOB announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the China Securities Regulatory Commission, or CSRC, and the Ministry of Finance, or MOF, which establishes a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by the PCAOB, the CSRC, or the MOF in the United States and the PRC, respectively. The PCAOB continues to be in discussions with the CSRC and the MOF to permit joint inspections in the PRC of audit firms that are registered with PCAOB and audit Chinese companies that trade on U.S. exchanges.

This lack of PCAOB inspections in China prevents the PCAOB from regularly evaluating audits and quality control procedures of any auditors operating in China, including our auditor and the auditors of

our joint ventures. As a result, investors may be deprived of the benefits of PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors 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.

## We do not currently intend to pay dividends on our securities, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the ADSs.

We have never declared or paid any dividends on our ordinary shares. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your ADSs at least in the near term, and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our shareholders have purchased the ADSs.

#### The market price for our ADSs may be volatile which could result in substantial loss to you.

The market price of our ADSs has been volatile. From March 17, 2016 to March 1, 2018, the closing sale price of our ADSs ranged from a high of \$41.14 to a low of \$11.26 per ADS.

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 competitive developments;
- regulatory developments affecting us, our customers or our competitors;
- announcements regarding litigation or administrative proceedings involving us;
- actual or anticipated fluctuations in our period-to-period operating results;
- changes in financial estimates by securities research analysts;
- additions or departures of our executive officers;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; and
- sales or perceived sales of additional ordinary shares or ADSs.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. For example, since August 2008, multiple exchanges in the United States and other countries and regions, including China, experienced sharp declines in response to the growing credit market crisis and the recession in the United States. As recently as July 2015, the exchanges in China experienced a sharp decline. Prolonged global capital markets volatility may affect overall investor sentiment towards our ADSs, which would also negatively affect the trading prices for our ADSs.

#### The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.

Our ordinary shares continue to be listed on the AIM market of the London Stock Exchange. The dual listing of our ordinary shares and the ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the AIM market. Furthermore, our ordinary shares trade on the AIM market of the London Stock Exchange

in the form of depository interests, each of which is an electronic book-entry interest representing one of our ordinary shares. However, the ADSs are backed by physical ordinary share certificates, and the depositary for our ADS program is unable to accept depository interests into its custody in order to issue ADSs. As a result, if an ADS holder wishes to cancel its ADSs and instead hold depository interests for trading on the AIM market or vice versa, the issuance and cancellation process may be longer than if the depositary could accept such depository interests.

Although our ordinary shares continue to be listed on the AIM market following our initial public offering in the United States completed in March 2016, we may decide at some point in the future to propose to our ordinary shareholders to delist our ordinary shares from the AIM market, and our ordinary shareholders may approve such delisting. We cannot predict the effect such delisting of our ordinary shares on the AIM market would have on the market price of the ADSs on the Nasdaq Global Select Market.

## Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may increase the risk of holding the ADSs.

Our share price is quoted on the AIM market of the London Stock Exchange in pence sterling, while the ADSs will trade on Nasdaq in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may result in temporary differences between the value of the ADSs and the value of our ordinary shares, which may result in heavy trading by investors seeking to exploit such differences. In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the pound sterling, the U.S. dollar equivalent of the proceeds that a holder of the ADSs would receive upon the sale in the United Kingdom of any shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in pound sterling on our shares represented by the ADSs could also decline.

#### Fluctuations in the value of the renminbi may have a material adverse effect on your investment.

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in 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, and the renminbi appreciated more than 20% against the U.S. dollar over the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the renminbi and U.S. dollar remained within a narrow band. In June 2010, China's People's Bank of China, or PBOC, announced that the PRC government would increase the flexibility of the exchange rate, and thereafter allowed the renminbi to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, on August 11, 12 and 13, 2015, the PBOC significantly devalued the renminbi by fixing its price against the U.S. dollar 1.9%, 1.6%, and 1.1% lower than the previous day's value, respectively. In 2016, the renminbi further depreciated against the U.S. dollar by approximately 6.7%, and from January 1, 2017 to December 31, 2017, the renminbi appreciated against the U.S. dollar by 6.0%.

Significant revaluation of the renminbi may have a material adverse effect on your investment. For example, to the extent that we need to convert U.S. dollars into renminbi for our operations, 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 U.S. dollars would affect our financial results reported in U.S. dollar terms regardless of any underlying change in our business or results of operations.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert renminbi into foreign currency.

## Securities traded on the AIM market of the London Stock Exchange may carry a higher risk than shares traded on other exchanges and may impact the value of your investment.

Our ordinary shares are currently traded on the AIM market of the London Stock Exchange. Investment in equities traded on AIM is perceived by some to carry a higher risk than an investment in equities quoted on exchanges with more stringent listing requirements, such as the New York Stock Exchange or the Nasdaq. This is because the AIM market imposes less stringent ongoing reporting requirements than those other exchanges. You should be aware that the value of our ordinary shares may be influenced by many factors, some of which may be specific to us and some of which may affect AIM-listed companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our ordinary shares, legislative changes and general economic, political or regulatory conditions, and that the prices may be volatile and subject to extensive fluctuations. Therefore, the market price of our ordinary shares underlying the ADSs may not reflect the underlying value of our company.

## The depositary for our ADSs gives us a discretionary proxy to vote our ordinary shares underlying your ADSs if you do not vote at shareholders' meetings, except in limited circumstances, which could adversely affect your interests.

Under the deposit agreement for the ADSs, the depositary gives us a discretionary proxy to vote our ordinary shares underlying your ADSs at shareholders' meetings if you do not vote, unless:

- we do not wish a discretionary proxy to be given;
- we are aware or should reasonably be aware that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would materially and adversely affect the rights of shareholders.

The effect of this discretionary proxy is that you cannot prevent our ordinary shares underlying your ADSs from being voted, absent the situations described above, and it may make it more difficult for shareholders to influence the management of our company. Holders of our ordinary shares are not subject to this discretionary proxy.

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

Holders of our ADSs do not have the same rights as 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 memorandum and articles of association, an annual general meeting and any extraordinary general meeting at which the passing of a special resolution is to be considered may be called with not less than 21 clear days' notice, and all other extraordinary general meetings may be called with not less than 14 clear days' notice. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. If we ask for your instructions, we will give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date and the depositary will send a notice to you about the upcoming vote and will arrange to deliver our voting materials to you. The depositary and its agents, however, 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 the ordinary shares underlying your ADSs. Furthermore, the depositary will not be liable 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 request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

## You may not receive distributions on our ADSs or any value for them if such distribution is illegal or if any required government approval cannot be obtained in order to make such distribution available to you.

Although we do not have any present plan to pay any dividends, the depositary of our ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying our ADSs, after deducting its fees and expenses and any applicable taxes and governmental charges. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities whose offering would require registration under the Securities Act but is not so properly registered or distributed under an applicable exemption from registration. The depositary may also determine that it is not reasonably practicable to distribute certain property. In these cases, the depositary may determine not to distribute such property. We have no obligation to register under the U.S. securities laws any offering of ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. This means that you may not receive distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of our ADSs.

#### Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.

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 either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is 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. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

## If we are classified as a passive foreign investment company, U.S. investors could be subject to adverse U.S. federal income tax consequences.

The rules governing passive foreign investment companies, or PFICs, can have adverse effects for U.S. investors for U.S. federal income tax purposes. The tests for determining PFIC status for a taxable year depend upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. As discussed in "Taxation—Material U.S. Federal Income Tax Considerations," we do not believe that we are currently a PFIC. Notwithstanding the foregoing, the determination of whether we are a PFIC

depends on particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. The fair market value of our assets is expected to depend, in part, upon (1) the market price of our ordinary shares and ADSs and (2) the composition of our income and assets, which will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. In light of the foregoing, no assurance can be provided that we are not currently a PFIC or that we will not become a PFIC in any future taxable year. Furthermore, if we are treated as a PFIC, then one or more of our subsidiaries may also be treated as PFICs.

If we are or become a PFIC, and, if so, if one or more of our subsidiaries are treated as PFICs, U.S. holders of our ordinary shares and ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferential tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. Whether U.S. holders of our ordinary shares or ADSs make (or are eligible to make) a timely qualified electing fund, or QEF, election or a mark-to-market election may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ordinary shares and ADSs and any distributions such U.S. holders may receive. We do not, however, expect to provide the information regarding our income that would be necessary in order for a U.S. holder to make a QEF election if we are classified as a PFIC. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ordinary shares and ADSs.

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

We are a company incorporated under the laws of the Cayman Islands, and substantially all of our assets are located outside 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. A substantial portion of the assets of these persons are located outside the United States. As a result, it may be difficult for you to effect service of process within the United States upon these persons. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors, all of whom are not residents in the United States and whose assets are located outside the United States. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

#### 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 deems 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.

#### ITEM 4. INFORMATION ON THE COMPANY

#### A. History and Development of the Company.

Our company was founded in 2000 by Hutchison Whampoa Limited (which in 2015 became a wholly owned subsidiary of CK Hutchison), a Hong Kong based multinational conglomerate with operations in over 50 countries. CK Hutchison is the ultimate parent company of our majority shareholder Hutchison Healthcare Holdings Limited.

We launched our Innovation Platform in 2002 with the establishment of our subsidiary Hutchison MediPharma. Our Innovation Platform is focused on the discovery and development of small-molecule compounds against novel but relatively well-characterized targets with global first-in-class potential against these targets, as well as compounds against validated targets to potentially be global best-in-class, next-generation therapies with a superior profile compared to existing approved drugs that act against these targets.

In the years since the launch of our Innovation Platform, we have assembled a leading drug research and development team in China to create a large scale and fully-integrated drug discovery and development operation covering chemistry, biology, pharmacology, toxicology, chemistry and manufacturing controls, clinical and regulatory and other functions, which work seamlessly together. Our approach has been to create a stable and supportive environment that allows our research and development team to innovate. We believe we have succeeded in this, and as of December 31, 2017, we and our collaboration partners discussed below have invested about \$500 million in the discovery and development activities of our Innovation Platform. This has resulted in a significant clinical pipeline consisting of eight small molecule tyrosine kinase inhibitors, which are currently being investigated in clinical studies in 36 target patient populations around the world.

We have taken a multi-source approach to funding which has been key to our ability to continuously support our Innovation Platform. We completed our initial public offering and listing on the AIM market of the London Stock Exchange in 2006 raising gross proceeds of approximately £40 million (equivalent to approximately \$75 million at the prevailing exchange rate at that time). We completed our initial public offering in the United States and listing on the Nasdaq Global Select Market in 2016, raising gross proceeds of approximately \$110.2 million, and we completed another underwritten public offering of securities in 2017, raising gross proceeds of approximately \$301.3 million. We have also utilized bank facilities in the aggregate principal amount of approximately \$30.0 million as of December 31, 2017. In addition, we have received government grants totaling approximately \$16.7 million and investments from other parties since our establishment, including investments by Mitsui & Co. Ltd., or Mitsui, one of our shareholders, totaling over \$15 million in the aggregate since 2010.

Moreover, to further our research and development activities, we have entered into a number of collaboration agreements for the research, development and commercialization of certain of our drug candidates with leading global pharmaceutical and healthcare companies, including Janssen in 2008 (subsequently terminated in 2015), AstraZeneca in 2011 and Eli Lilly in 2013. In 2012, we also entered into a joint venture collaboration with Nestlé Health Science pursuant to which we share research and development expenses and receive payments for certain services. Under the terms of these collaborations, our partners have made certain upfront, milestone and service fee payments, clinical cost reimbursements and equity contributions, totaling approximately \$260.0 million since 2008. In addition to financial support, we benefit from these arrangements by gaining access to our partners' scientific, development, regulatory and commercial capabilities.

Since 2001 to December 31, 2017, we have also developed a profitable Commercial Platform in China, which includes our non-consolidated joint ventures Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan, which have paid out dividends to our company and our partners totaling approximately \$316.2 million. Our Commercial Platform encompasses two core areas: Prescription Drugs and Consumer Health products.

Our core Prescription Drugs business is conducted through the following two joint ventures for which we nominate the management and run the day-to-day operations:

• Shanghai Hutchison Pharmaceuticals, which was formed in 2001 and primarily manufactures, markets and distributes approximately 74 prescription drug products, originally contributed by our joint venture partner, as well as third-party prescription drugs. As of December 31, 2017, it held 74 registered drug licenses in China. 50% of this joint venture is owned by us and 50% by Shanghai

Pharmaceuticals, a leading pharmaceutical company in China listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, and

• Hutchison Sinopharm, which was formed in 2014 and focuses on providing logistics services to and distributing and marketing prescription drugs manufactured by pharmaceutical companies. 51% of this joint venture is owned by us and 49% is owned by Sinopharm, a leading distributor of pharmaceutical and healthcare products and a leading supply chain service provider in China listed on the Hong Kong Stock Exchange.

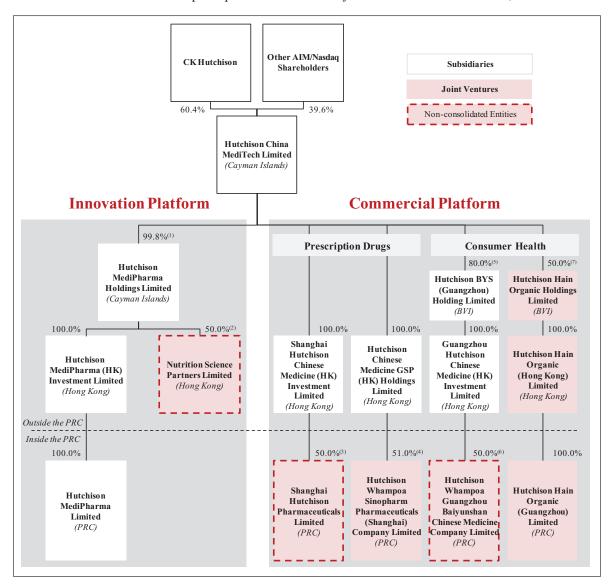
Through these joint ventures, we have steadily built up an extensive sales and distribution network across China, with approximately 2,300 medical sales representatives as of December 31, 2017. Net income attributable to our company from our Prescription Drugs business was \$15.9 million, \$61.1 million and \$29.0 million for the years ended December 31, 2015, 2016 and 2017, respectively. Net income attributable to our company from our Prescription Drugs business included one-time gains of \$40.4 million in 2016, primarily from land compensation received by Shanghai Hutchison Pharmaceuticals from the Shanghai government. In 2017, net income attributable to our company from our Prescription Drugs business included one-time gains of \$2.5 million in government subsidies received by Shanghai Hutchison Pharmaceuticals from the Shanghai government.

Our Consumer Health business, which we do not consider to be core to our overall business and strategy, includes two joint ventures: Hutchison Baiyunshan, a joint venture which was formed in 2005 with Guangzhou Baiyunshan and focuses primarily on the manufacture, marketing and distribution of over-the-counter pharmaceutical products in China, and Hutchison Hain Organic, a joint venture which was established in 2009 and markets and distributes a broad range of natural and organic consumer products under brands owned by Hain Celestial in nine Asian territories. We also manufacture and distribute various infant nutrition products. Net income attributable to our company's shareholders from our Consumer Health business subsidiaries and joint ventures decreased marginally from \$9.3 million in 2015 to \$9.2 million in 2016 and increased by 19.7% to \$11.0 million in 2017.

As of December 31, 2017, we were the second largest AIM-listed company in terms of market capitalization.

#### **Our Organizational Structure**

The chart below shows our principal subsidiaries and joint ventures as of March 1, 2018.



#### Notes:

- (1) Employees of Hutchison MediPharma Limited hold the remaining 0.2% shareholding.
- (2) Nestlé Health Science S.A. is the other 50% joint venture partner.
- (3) Shanghai Pharmaceuticals Holding Co., Ltd. is the other 50% joint venture partner.
- (4) Sinopharm Group Co. Ltd. is the other 49% joint venture partner.
- (5) Dian Son Development Limited holds the other 20% interest.
- (6) Guangzhou Baiyunshan Pharmaceutical Holdings Company Limited is the other 50% joint venture partner.
- (7) The Hain Celestial Group, Inc. is the other 50% joint venture partner.

#### B. Business Overview.

#### Overview

We are an innovative biopharmaceutical company based in China aiming to become a global leader in the discovery, development and commercialization of targeted therapies for oncology and immunological diseases. Our approximately 360-person strong scientific team has created and developed a deep portfolio of eight drug candidates that are being investigated in active or completed clinical studies in 36 target patient populations around the world. These drug candidates are being developed to treat a wide spectrum of diseases, including solid tumors, hematological malignancies, and cover immunology applications which we believe address significant unmet medical needs and represent large commercial opportunities. Many of these drugs have the potential to be first-in-class or best-in-class. Our success in research and development has led to partnerships with leading global pharmaceutical companies, including AstraZeneca, Eli Lilly and Nestlé Health Science.

For seventeen years, we and our partners have invested about \$500 million in building our Innovation Platform. Since inception to December 31, 2017, our Innovation Platform's drug pipeline has dosed over 3,500 patients/subjects in clinical trials of our drug candidates, with over 700 dosed in 2017, primarily driven by the enrollment of the six Phase III studies on savolitinib, fruquintinib, and sulfatinib.

Our core research and development strategy has been to take a highly rigorous and focused cross-disciplinary approach to design uniquely selective small molecule tyrosine kinase inhibitors deliberately engineered to improve drug efficacy and reduce known side effects. Accordingly, we believe our drug candidates such as savolitinib (targeting the mesenchymal epithelial transition factor, or c-Met), HMPL-523 (targeting the spleen tyrosine kinase, or Syk) and HMPL-453 (targeting fibroblast growth factor receptors, or FGFR1/2/3) have the potential to be global first-in-class therapies. In the cases of fruquintinib (targeting vascular endothelial growth factor receptor, or VEGFR 1/2/3), sulfatinib (targeting VEGFR/FGFR1/colony stimulating factor-1 receptor, or CSF-1R), epitinib (targeting epidermal growth factor receptor activating mutations, or EGFRm+, with brain metastasis), theliatinib (targeting EGFR wild-type) and HMPL-689 (targeting phosphoinositide 3-kinase  $\delta$ , or PI3K $\delta$ ), we believe our drug candidates are sufficiently selective and/or differentiated to be potential global best-in-class, next-generation therapies. We also continue to focus on maximizing patient outcomes through clinical studies involving combinations or rotations of treatment of our drug candidates with other targeted therapies, immuno-oncology agents and chemotherapies.

In June 2017, we completed our first NDA submission, which was for fruquintinib in patients with third-line colorectal cancer in China. We also initiated our first global Phase III study in oncology, for savolitinib in patients with papillary renal cell carcinoma. Each triggered milestone payments from our partners Eli Lilly and AstraZeneca, respectively, and each represents a major achievement for Chi-Med and for the biotechnology industry in China.

In our view, the China oncology market represents a substantial and fast-growing market opportunity expected to be supported by China's increasing emphasis on innovation combined with its rapidly improving regulatory environment. We believe our well-established presence in China, combined with our ability to deliver global-quality innovation, positions us well to address the major unmet medical needs in the China oncology market as well as to identify opportunities for our differentiated assets in the global market.

In addition to our Innovation Platform, we have established a profitable Commercial Platform in China which manufactures, markets and distributes prescription drugs and consumer health products. This Commercial Platform has been built over the past 17 years and focuses on two business areas. The first is our core Prescription Drugs business operated by joint ventures, Shanghai Hutchison Pharmaceuticals and Hutchison Sinopharm, which operate a network of approximately 2,300 medical sales representatives covering about 22,500 hospitals in over 300 cities and towns in China as of December 31, 2017. The second

is our Consumer Health business primarily operated by our joint venture, Hutchison Baiyunshan, which is a profitable and cash-generating business selling household-name, over-the-counter pharmaceutical products. Our Commercial Platform's total consolidated sales were \$205.2 million in 2017, an increase of 13.5% compared to \$180.9 million in 2016, mainly resulting from growth in Hutchison Sinopharm's Prescription Drug commercial services business. We and our joint ventures manufacture and sell about 4.6 billion doses of medicines a year, in the aggregate, through our well-established GMP-certified manufacturing bases. We intend to leverage this Commercial Platform to support the launch of products from our Innovation Platform if they are approved for use in China. Outside of China, we intend to commercialize our products, if approved, in the United States, Europe and other major markets on our own and/or through partnerships with leading biopharmaceutical companies.

#### **Our Innovation Platform**

Figure 1: Pipeline Chart

rogram	Target	Partner	TPP Number/Indication	LatestStatus	Line	TPP	Combo therapy	Site	Preclin.	Ph.I	Proof-of-concept	Pivotal/P
savolitinib AZD6094)	c-Met		1. Papillary renal cell carcinoma			c-Met-driven		Global				•
		AstraZer	2. Papillary renal cell carcinoma	NCI Ph.II - savo vs. sunitinib vs. cabozan. vs. crizot.	All	All		US				
			3. Papillary renal cell carcinoma	Ph.II enrolling	-	All	durvalumab (PD-L1)	UK/Sp			i i i	
			4. Clear cell renal cell carcinoma	Ph.II enrolling	2 <sup>nd</sup>	VEGF TKI refractory		UK/Sp				
			5. Clear cell renal cell carcinoma	Ph.II enrolling	2 <sup>nd</sup>	VEGF TKI refractory	durvalumab (PD-L1)	UK/Sp				
			6. Non-small cell lung cancer	Ph.II enrolling; planning next stage initiation 2018	2 <sup>nd</sup>	EGFRTKI refractory	Tagrisso® (T790M)	Global				1
			7. Non-small cell lung cancer	Ph.II enrolling; pivotal decision pending	3 <sup>rd</sup>	EGFR/T790M TKI	Tagrisso®(T790M)	Global				1
			8. Non-small cell lung cancer	Ph.II enrollment complete: pivotal under discussion		EGFR TKI refractory		China				•
		č	9. Non-small cell lung cancer	Ph.II enrolling		c-Met-driven	(23.1)	China			<b>→</b>	
		2	10. Lung cancer	Ph.II enrolling		c-Met-driven		China				
			11. Gastriccancer	Ph.II enrolling		c-Met+		SK/PRC				
			12. Gastriccancer	Ph.II enrolling		c-Met+	docetaxel (chemo)	SK			<b>→</b>	
			13. Gastriccancer	Ph.II enrolling		c-Met O/E	docetaxel (chemo)	SK			-	
			14. Prostate cancer	CCTG Ph.II enrolling - umbrella trial		C-Met-driven	doceaner (criemo)	Can				
			14. PTOState Cancer	cerd First enrolling - dilibrena diai	1 /2	C-MEE driver		Call				
			15. Colorectal cancer	Ph.III met all endpoints; NDA submitted Jun 2017	3 <sup>rd</sup>			China			( <u> </u>	
	VEGFR 1/2/3	dilly	16. Non-small cell lung cancer	Ph.III fully enrolled; report top-line results late 2018	3 <sup>rd</sup>	All		China			n/a	
quintinib			17. Non-small cell lung cancer	Ph.II enrolling		All	Iressa®(EGFR)	China				
	1/2/3		18. Caucasian bridging	Ph.I enrolling		All comers		US				
			19. Gastric cancer	Ph.III enrolling	2 <sup>nd</sup>	All	paclitaxel (chemo)	China				
				10000000000000000000000000000000000000								
Sulfatinib			20. Pancreatic NET	Ph.III enrolling		All		China				•
	VEGFR/		21. Non-pancreatic NET	Ph.III enrolling	1 <sup>st</sup>	All		China		· ·		•
	CSF-1R/		22. Caucasian bridging	Ph.I enrolling	-	All comers		US		•		
	FGFR1		23. Medullary thyroid ca.	Ph.II enrollment complete	2 <sup>nd</sup>	Radiotherapy ref.		China				
	TUTKI		24. Differentiated thyroid ca.	Ph.II enrollment complete	2 <sup>nd</sup>	Radiotherapy ref.		China				
			25. Biliary tract cancer	Ph.II enrolling	2 <sup>nd</sup>	Chemo ref.		China			•	
			26. Non-small cell lung cancer	Preparing for Ph.III; target initiation 2018	1 <sup>st</sup>	EGFRm+brain mets		China		ji i		4
pitinib	EGFRm+		27. Glioblastoma	Ph.lb/II enrolling		EGFR+		China				4
			27. diluulastuilla	PILID/II EIIIOIIIIIg		EUFRT		Cillia			1.4	
heliatinib			28. Solid tumors	Ph.I enrollment complete		All comers		China		•		
	EGFR WT		29. Esophageal cancer	Ph.Ib expansion enrolling	1 <sup>st</sup>	EGFR WT		China		-		
HMPL-523			30. Immunology	Ph.I complete; preparing for Ph.II	-	Healthy volunteers		Aus		•		
	Syk		31. Immunology	Ph.I dose escalation		Healthy volunteers		China				
	Jyk		32. Hematological cancers	Ph.I enrolling	2 <sup>nd</sup> /3 <sup>rd</sup>	All comers		Aus		}		
			33. Lymphoma	Ph.I enrolling		All comers		China				
			34. Hematological cancers	Ph.I complete; preparing for Ph.II	27	Healthy volunteers		Aus		-		
MPL-689	РІЗКδ		35. Lymphoma	Ph.I enrolling		All comers		China				
			o o i agricina	, mismoning	2 ,0			annia.				
MPL-453	FGFR		36. Solid tumors	Ph.I enrolling	-	All comers		Aus		•		
1PL-433	1/2/3		37. Solid tumors	Ph.I enrolling	-	All comers		China				
	NE E	Noctie	Illearnthus calitie (Industi \	HADL OUT referentiation IND submitted	and	FACA refractor:		Aug (Chi				
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ISP DC2	TBD	Nestle	Immunology	IND end of 2018				China				
		Science										
lultiple	TBD		Oncology	Four small molecule/antibody programs in preclin.				TBD				

Notes: TPP = target patient population (TPP numbers are included for reference throughout the discussion below); Proof-of-concept = Phase Ib/II study (the dashed lines delineate the start and end of Phase Ib); combo = in combination with; brain mets = brain metastasis; VEGFR = vascular endothelial growth factor receptor; TKI = tyrosine kinase inhibitor; EGFR = epidermal growth factor receptor;

NET = neuroendocrine tumors; ref = refractory, which means resistant to prior treatment; T790M= EGFR resistance mutation; EGFRm+ = EGFR activating mutations; EGFR+ = EGFR gene amplification; EGFR WT = EGFR wild-type; 5ASA = 5-aminosalicylic acids; chemo = chemotherapy; c-Met+ = c-Met gene amplification; c-Met O/E = c-Met over-expression; FGFR = fibroblast growth factor receptor; CSF-1R = colony stimulating factor-1 receptor; NCI = U.S. National Cancer Institute; CCTG = Canadian Cancer Trial Group; Aus = Australia; Can = Canada; SK = South Korea; PRC = People's Republic of China; Sp = Spain; UK = United Kingdom; US = United States; Global = >2 countries.

#### Overview of Our Clinical-stage Drug Candidates

#### Savolitinib (AZD6094/HMPL-504)

Savolitinib is a potential global first-in-class inhibitor of the mesenchymal epithelial transition factor, or c-Met, receptor tyrosine kinase, an enzyme which has been shown to function abnormally in many types of solid tumors. We designed savolitinib as a potent and highly selective oral inhibitor which through chemical structure modification addresses renal toxicity, the primary issue that halted development of several other selective c-Met inhibitors. In clinical studies to date, involving over 500 patients, savolitinib has shown promising signs of clinical efficacy and acceptable safety profile in patients with c-Met gene alterations in papillary renal cell carcinoma, non-small cell lung cancer, colorectal cancer, and gastric cancer.

We are currently testing savolitinib in partnership with AstraZeneca in multiple Phase Ib/II studies, both as a monotherapy and in combination with other targeted therapies. In June 2017, we initiated SAVOIR, a global pivotal Phase III, open-label, randomized multi-center registration study of savolitinib in c-Met driven metastatic papillary renal cell carcinoma. This is the first pivotal study ever conducted in c-Met driven papillary renal cell carcinoma and the first molecularly selected trial in renal cell carcinoma. We expect to complete enrollment in late 2019.

At the 2017 World Conference on Lung Cancer, we presented preliminary safety and clinical activity data of savolitinib when given in combination with either Tagrisso or Iressa in two Phase Ib/II proof-of-concept trials conducted in patients with EGFRm+ non-small cell lung cancer with Met-amplification who had progressed following first-line treatment with an EGFR inhibitor. In both trials, the addition of savolitinib (600 mg once daily) to Tagrisso (80 mg once daily) or Iressa (250 mg once daily) demonstrated preliminary anti-tumor activity. We and AstraZeneca have now agreed on the next stage of development in non-small cell lung cancer patients as discussed below.

Phase II gastric cancer studies are ongoing in China, and a multi-arm Phase II study, named the VIKTORY study, is being conducted at Samsung Medical Center in South Korea. Over 850 gastric cancer patients have been screened in these studies, and those patients with confirmed c-Met driven disease are being treated with either savolitinib monotherapy or savolitinib in combination with Taxotere. We presented preliminary data from these studies in 2017, and the China study concluded that savolitinib monotherapy demonstrated promising anti-tumor efficacy. We believe the potential benefit to the patients warrants further exploration with Phase II enrollment continuing in China. The VIKTORY Phase II study is ongoing, and we expect to present preliminary data at a major scientific conference in 2018.

The terms of our collaboration with AstraZeneca are governed by a December 2011 agreement under which we granted AstraZeneca co-exclusive, worldwide rights to develop, and exclusive worldwide rights to manufacture and commercialize savolitinib for all diagnostic, prophylactic and therapeutic uses. We refer to this agreement as the AstraZeneca Agreement. Under the original terms of the AstraZeneca Agreement, we and AstraZeneca agreed to share the development costs for savolitinib in China, with AstraZeneca being responsible for the development costs for savolitinib in the rest of the world. In August 2016, we and AstraZeneca agreed to amend the AstraZeneca Agreement, whereby we agreed to contribute up to \$50 million, spread primarily over three years, to the joint development costs of the global

pivotal Phase III study in patients with c-Met driven papillary renal cell carcinoma. Subject to approval in the papillary renal cell carcinoma indication, we will receive a five percentage point increase in the global tiered royalty rate payable on savolitinib sales across all indications in all regions excluding China. Taking into account such increase, AstraZeneca is obligated to pay us tiered royalties from 14.0% to 18.0% annually on all sales made of any product outside of China. After total aggregate sales of savolitinib have reached \$5 billion outside of China, the royalty will step down over a two year period, to an ongoing royalty rate of 10.5% to 14.5%. See Item 4.B. "Business Overview—Overview of Our Collaborations—AstraZeneca" for more details.

#### Fruquintinib (HMPL-013)

Fruquintinib is a highly selective and potent oral inhibitor of vascular endothelial growth factor receptor, or VEGFR, and consequently we believe that it has the potential to be a global best-in-class VEGFR inhibitor for many types of solid tumors. Based on pre-clinical and clinical data to date, fruquintinib's kinase selectivity has been shown to reduce off-target toxicity. This allows for drug exposure that is able to fully inhibit VEGFR, a receptor tyrosine kinase which contributes to angiogenesis, the buildup of new blood vessels around a tumor, thereby contributing to the growth of tumors, and use in potential combinations with other agents such as chemotherapies, targeted therapies and immunotherapies. We believe these are points of meaningful differentiation versus other small molecule VEGFR inhibitors that have already been approved, such as Sutent, Nexavar and Stivarga, and can potentially significantly expand the use and market potential of fruquintinib.

In partnership with Eli Lilly, we are currently studying fruquintinib in colorectal cancer, non-small cell lung cancer and gastric cancer in China.

In June 2017, the CFDA acknowledged acceptance of the NDA for fruquintinib for the treatment of patients with advanced colorectal cancer. Fruquintinib was subsequently awarded priority review status in view of its significant clinical value, according to a CFDA announcement in September 2017. The NDA is supported by data from the successful FRESCO study, a Phase III pivotal registration trial of fruquintinib in 416 patients with locally advanced or metastatic colorectal cancer in China, which was highlighted in an oral presentation at the American Society of Clinical Oncology Annual Meeting in June 2017.

In February 2018, we completed patient enrollment of the FALUCA study, a Phase III pivotal trial of fruquintinib in 527 advanced, third-line, non-small cell lung cancer patients in China. Top-line data are expected to be reported in late 2018 when the overall survival data are mature, and subject to a positive outcome, would be followed by a second NDA submission thereafter. The FALUCA study was initiated following a similar Phase II clinical trial in 91 third-line non-small cell lung cancer patients that succeeded in meeting its primary efficacy endpoint of progression-free survival reporting only one treatment-related adverse event greater than or equal to grade 3, or grade ≥3, based on the National Cancer Institute's Common Terminology Criteria for Adverse Event, or CTC, which is a set of criteria for the standardized classification of adverse effects of drugs used in cancer therapy (with 1 and 2 being relatively mild and higher numbers (up to 5) being more severe), which was hypertension (8.2%). Results were highlighted in an oral presentation at the World Conference on Lung Cancer in December 2016.

We believe the most significant global market opportunity for fruquintinib will come by combining it with other oncology therapies such as chemotherapy, immunotherapy and other tyrosine kinase inhibitors for use in earlier-line treatments. Along with the FALUCA study, fruquintinib is concurrently being studied in a Phase II study in combination with Iressa in a first-line setting for patients with advanced or metastatic non-small cell lung cancer. In October 2017, we reported preliminary clinical activity, safety and tolerability data of fruquintinib in combination with Iressa in patients with EGFRm+ non-small cell lung cancer. These data were from an ongoing Phase II proof-of-concept trial which was initiated in January 2017 and presented at the World Conference on Lung Cancer in October 2017.

In October 2017, we initiated the FRUTIGA study, a pivotal Phase III clinical trial of fruquintinib in combination with Taxol in second-line gastric cancer. The FRUTIGA study was initiated following the results of an open-label, multi-center, Phase Ib dose finding/expansion study of fruquintinib in combination with Taxol in second-line gastric cancer, which established a well-tolerated combination dose with encouraging efficacy.

We have established a manufacturing (formulation) facility in Suzhou, China, which now produces Phase III clinical supplies and will be used to produce fruquintinib, as well as our other drugs, for commercial supply if approved.

In December 2017, we also initiated a multi-center, open-label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of fruquintinib in U.S. patients with advanced solid tumors.

#### Sulfatinib (HMPL-012)

Sulfatinib is an oral drug candidate with a unique angio-immuno kinase profile which provides both anti-angiogenesis effect and, we believe, activates and effectively enhances the body's immune system, specifically T-cells. Importantly, in 2016 we presented pre-clinical data that show sulfatinib, in addition to inhibiting VEGFR and FGFR1, is a potent inhibitor of CSF-1R, a signaling pathway involved in blocking the activation of tumor-associated macrophages, which cloak cancer cells from attack from T-cells.

We are currently conducting six clinical trials of sulfatinib and retain all rights to sulfatinib worldwide. In early 2017, we completed a Phase II study in neuroendocrine tumor patients in China and reported the results from this Phase II study in a total of 81 patients which indicated that sulfatinib was well tolerated with highly encouraging efficacy in patients with both pancreatic neuroendocrine tumors and extrapancreatic neuroendocrine tumors. Importantly, for purposes of our potential global development strategy, there were 14 patients who had progressed after treatment with systemic therapies (e.g., Sutent and Afinitor) and all benefited from sulfatinib treatment. Based on the promising Phase II efficacy data and tolerability in patients with advanced neuroendocrine tumors, we initiated two randomized Phase III trials in China along with development in the United States.

Sulfatinib is the first oncology candidate that we have taken through proof-of-concept in China and expanded to a U.S. clinical study ourselves. A Phase I study in cancer patients in the United States is now close to completion. Having established that the 300 mg once daily dose used in China is safe in U.S. patients, we are now also enrolling a final cohort to establish that a 400 mg dose is also safe in U.S. patients. We are currently in final planning stage for an expansion of sulfatinib development in the United States into a multi-arm proof-of-concept study to explore efficacy and safety in both Sutent and Afinitor refractory pancreatic neuroendocrine tumor patients as well as patients with biliary tract cancer (also known as cholangiocarcinoma).

We initiated a Phase II study in patients with locally advanced or metastatic radioactive iodinerefractory differentiated thyroid cancer or medullary thyroid cancer in China in March 2016. We also initiated a further Phase II study in patients with biliary tract cancer in January 2017.

#### Epitinib (HMPL-813)

A significant portion of patients with non-small cell lung cancer go on to develop brain metastasis. Patients with brain metastasis suffer from poor prognosis. Epitinib is a potent and highly selective oral EGFR inhibitor which has demonstrated brain penetration and efficacy in pre-clinical and now clinical studies. EGFR inhibitors have revolutionized the treatment of non-small cell lung cancer with EGFR activating mutations. However, approved EGFR inhibitors such as Iressa and Tarceva cannot penetrate the blood-brain barrier effectively, leaving the majority of patients with brain metastasis without an effective targeted therapy. We currently retain all rights to epitinib worldwide.

In December 2016, we presented positive results from our Phase Ib proof-of-concept study in non-small cell lung cancer patients with EGFR activating mutations and brain metastasis, in which epitinib demonstrated encouraging tumor response efficacy in both the lung and the brain. We expect to decide the Phase III dose in early 2018 and initiate Phase III shortly thereafter. If epitinib is able to provide clinical benefit to non-small cell lung cancer patients with brain metastasis in these studies, we believe that, subject to regulatory approval, we will be well-positioned to address a major global unmet medical need.

Additionally, in March 2018, we initiated a Phase Ib/II proof-of-concept study of epitinib in glioblastoma patients with EGFR gene amplification in China. Glioblastoma is a primary brain cancer that harbors high levels of EGFR gene amplification. This Phase Ib/II study will be a multi-center, single-arm, open-label study to evaluate the efficacy and safety of epitinib as a monotherapy in patients with EGFR gene amplified, histologically confirmed glioblastoma.

#### Theliatinib (HMPL-309)

Like epitinib, theliatinib is a novel molecule EGFR inhibitor under investigation for the treatment of solid tumors. Tumors with wild-type EGFR activation, for instance, through gene amplification or protein over-expression, are less sensitive to current EGFR tyrosine kinase inhibitors, Iressa and Tarceva, due to sub-optimal binding affinity. Theliatinib has been designed with strong affinity to the wild-type EGFR kinase and has been shown to be five to ten times more potent than Tarceva. Consequently, we believe that theliatinib could benefit patients with esophageal and head and neck cancer, tumor-types with a high incidence of wild-type EGFR activation. We currently retain all rights to theliatinib worldwide.

We are currently conducting a Phase I dose escalation study for theliatinib, with preliminary activity observed, and have initiated a Phase Ib study in patients with esophageal cancer with a high level of EGFR activation.

#### **HMPL-523**

We believe HMPL-523 is a potential global first/best-in-class oral inhibitor targeting spleen tyrosine kinase, or Syk, a key protein involved in B-cell signaling. Modulation of the B-cell signaling system has been proven to significantly advance the treatment of certain chronic immune diseases, such as rheumatoid arthritis as well as hematological cancers. To date, only monoclonal antibody immune modulators, which seek to use the patient's own immune system to treat the disease, have been approved. As an oral drug candidate, we believe HMPL-523 has important advantages over intravenous monoclonal antibody immune modulators in rheumatoid arthritis in that as small molecule compounds clear the system faster, thereby reducing the risk of infections from sustained suppression of the immune system.

Moreover, other drug development companies have tried to design small molecule Syk inhibitors for the treatment of chronic immune diseases, but designing an efficacious and safe Syk inhibitor has proven to be exceptionally difficult. No drug products targeting Syk have been approved to date due to severe off-target toxicity, such as hypertension, as a result of poor kinase selectivity. HMPL-523 is a potent and highly selective oral inhibitor specifically designed to overcome these off-target toxicity issues. We currently retain all rights to HMPL-523 worldwide.

With respect to the treatment of hematological cancers, Gilead Sciences Inc., or Gilead, and Takeda Pharmaceutical Company Ltd., or Takeda, both published in late 2015 encouraging proof-of-concept data showing strong signals of efficacy for their respective small molecule Syk inhibitors. The data are consistent with the major clinical successes and drug approvals in recent years of inhibitors targeting other kinases in the B-cell signaling pathway such as Bruton's tyrosine kinase, or BTK, and phosphoinositide 3-kinase  $\delta$ , or PI3K $\delta$ . While these BTK and PI3K $\delta$  inhibitors have been successful, resistance to these inhibitors can emerge over time, leading to loss in efficacy, and new targets in B-cell signaling such as Syk are potential solutions to this problem.

Our Phase I clinical trial in healthy volunteers completed a single ascending dose segment in mid-2015, where a single dose is given and the volunteers are observed and tested to confirm safety, and the results were well above the expected efficacious dose. The multiple ascending dose segment of the trial, where multiple doses are given to learn how the drug candidate is processed within the body was successfully completed in October 2015. We have submitted our U.S. immunology Investigational New Drug, or IND, application and engaged with the FDA around our plan for development in rheumatoid arthritis. We are now preparing to submit additional data to the FDA after which we will consider our U.S. development strategy in immunology.

In addition, in early 2016 we initiated a Phase I trial in Australia in patients with relapsed and/or refractory B-cell non-Hodgkin's lymphoma or chronic lymphocytic leukemia for whom there is no standard therapy. In mid-2016, we received clearance from the CFDA on our hematological cancer IND application and as a result, in January 2017, we started Phase I dose escalation in patients with B-cell non-Hodgkin's lymphoma or chronic lymphocytic leukemia in China. We are now in the process of increasing the number of clinical sites in Australia and China to support Phase Ib/II expansion in a broad range of indolent non-Hodgkin's lymphoma sub-types. We target to present dose escalation and expansion results, including preliminary proof-of-concept data, at a major scientific conference later in 2018.

We believe the market potential for a successful Syk inhibitor is substantial. To our knowledge, we are the only company worldwide, other than Gilead, developing Syk inhibitors for chronic immune diseases as well as oncology.

#### **HMPL-689**

HMPL-689 is a novel, highly selective and potent small molecule inhibitor targeting the isoform PI3K $\delta$ , a key component in the B-cell receptor signaling pathway. We have designed HMPL-689 with superior PI3K $\delta$  isoform selectivity, in particular to not inhibit PI3K $\gamma$  (gamma), to minimize the risk of serious infection caused by immune suppression. HMPL-689's strong potency, particularly at the whole blood level, also allows for reduced daily doses to minimize compound related toxicity, such as the high level of liver toxicity observed with the first-generation PI3K $\delta$  inhibitor Zydelig. HMPL-689's pharmacokinetic properties have been found to be favorable with good oral absorption, moderate tissue distribution and low clearance in pre-clinical pharmacokinetic studies. We also expect HMPL-689 will have low risk of drug accumulation and drug-to-drug interaction. Given this, we believe that HMPL-689 has the potential to be a global best-in-class PI3K $\delta$  agent. We currently retain all rights to HMPL-689 worldwide.

In 2016, we completed a Phase I, first-in-human, dose escalation study in healthy adult volunteers in Australia to evaluate the pharmacokinetics and safety profile following single oral dosing HMPL-689. Results were as expected with linear pharmacokinetics properties and good safety profile.

We subsequently received IND clearance in China and then initiated a Phase I dose escalation and expansion study in patients with hematologic malignancies in August 2017.

#### **HMPL-453**

HMPL-453 is a novel, potentially first-in-class, highly selective and potent small molecule inhibitor that targets FGFR 1/2/3, a sub-family of receptor tyrosine kinases. Aberrant FGFR signaling has been found to be a driving force in tumor growth (through tissue growth and repair), promotion of angiogenesis and resistance to anti-tumor therapies. To date, there are no approved therapies specifically targeting the FGFR signaling pathway. In pre-clinical studies, HMPL-453 demonstrated superior kinase selectivity and safety profile as well as strong anti-tumor potency, as compared to drug candidates in the same class. Abnormal FGFR gene alterations are believed to be the drivers of tumor cell proliferation in several solid tumor settings. We currently retain all rights to HMPL-453 worldwide.

In June 2017, we initiated a Phase I/II clinical trial in China to evaluate safety, tolerability, pharmacokinetics and preliminary efficacy of HMPL-453 monotherapy in patients with solid tumors harboring FGFR genetic alterations. This study complements the first-in-human Phase I clinical trial in Australia that was initiated in February 2017.

For more detailed information on the pre-clinical and clinical studies of these and our other drug candidates, please see "—Our Clinical Pipeline."

#### **Our Commercial Platform**

Our Commercial Platform is principally operated through joint ventures with three of the largest China-based healthcare conglomerates, Shanghai Pharmaceuticals, Sinopharm and Guangzhou Baiyunshan. We are currently focusing primarily on the distribution and manufacture of cardiovascular and anti-viral products, as well as the distribution of third-party products such as Concor, a cardiovascular drug from Merck Serono Co., Ltd., or Merck Serono, and Seroquel, a drug for the treatment of various psychiatric disorders from AstraZeneca. Our Commercial Platform has generated substantial cashflow over the years and will serve to help bring products from our Innovation Platform to market quickly and efficiently in China upon regulatory approval. Net income attributable to our company from our Commercial Platform was \$25.2 million \$70.3 million and \$40.0 million for the years ended December 31, 2015, 2016 and 2017, respectively. Net income attributable to our company from our Prescription Drugs business included one-time gains of \$40.4 million and \$2.5 million in the years ended December 31, 2016 and 2017, respectively, net of tax, from land compensation and other government subsidies paid to Shanghai Hutchison Pharmaceuticals by the Shanghai government.

#### Our Research and Development Approach

The strategy of our research and development program is to differentiate ourselves from companies developing and commercializing competing kinase inhibitors with a chemistry-focused approach. Our approach focuses on the development of kinases inhibitors with:

- unique selectivity to limit target-based toxicity,
- high potency to optimize the dose selection with the objective to lower the required dose and thereby limit compound-based toxicity,
- chemical structures deliberately engineered to improve drug exposure in the targeted tissue, and
- ability to be combined with other therapeutic agents.

Our approach consists of two main pillars, which we believe provides a balanced risk profile for our Innovation Platform: (i) developing synthetic compounds against novel targets with global first-in-class potential, which includes savolitinib (targeting c-Met), HMPL-523 (targeting Syk) and HMPL-453 (targeting FGFR1/2/3); and (ii) developing synthetic compounds against validated targets with clear differentiation to potentially be a global best-in-class/next-generation therapy in their respective categories, including fruquintinib (targeting VEGFR1/2/3), sulfatinib (targeting VEGFR1/CSF-1R), epitinib (targeting EGFRm+ brain metastasis), theliatinib (targeting EGFR wild type) and HMPL-689 (targeting PI3Kδ).

#### **Our Clinical Pipeline**

We are developing many of our drug candidates against multiple indications, which in some cases are common to one or more of our drug candidates.

#### Savolitinib c-Met Inhibitor

We first became interested in studying c-Met over a decade ago as it became clear that c-Met functions abnormally in many types of solid tumors and as such increasingly represented an important possible target in the treatment of cancer. We designed savolitinib as a potent and highly selective oral inhibitor, which through chemical structure modification addressed renal toxicity, the primary issue that has prevented c-Met inhibitors developed by other biopharmaceutical companies from gaining regulatory approval.

#### **Mechanism of Action**

C-Met, which is also known as hepatocyte growth factor receptor, or HGFR, is a signaling pathway that has specific roles in normal mammalian growth and development. However, the HGFR pathway has also been shown to function abnormally in a range of different cancers, primarily through c-Met gene amplification, c-Met over-expression and gene mutations. The aberrant activation of c-Met has been demonstrated to be highly correlated in many cancer indications, including kidney, lung, gastric, colorectal, esophageal and brain cancer, and plays a major role in cancer pathogenesis (i.e., the development of the cancer), including tumor growth, survival, invasions, metastasis, the suppression of cell death as well as tumor angiogenesis. As a result, c-Met has become a widely investigated anti-cancer target in recent years with several c-Met inhibitors under development by different companies, although to date none have received regulatory approval.

C-Met also plays a role in drug resistance in many tumor types. For instance, c-Met gene amplification has been found in non-small cell lung cancer and colorectal cancer following anti-EGFR treatment, leading to drug resistance. Furthermore, c-Met over-expression has been found to emerge in renal cell carcinoma following anti-VEGFR treatment.

#### Savolitinib Research Background

Around the time of the 2008 American Association for Cancer Research meetings, selective c-Met compounds were unveiled by multinational pharmaceutical companies such as Pfizer Inc. (PF-04217903), Janssen (JNJ-38877605) as well as biotechnology companies including Incyte Corporation (INC280, which was later licensed to Novartis International AG, or Novartis) and SGX Pharmaceuticals (SGX-523, which was later licensed to Eli Lilly). These compounds all had positive pre-clinical data that supported their high c-Met selectivity and pharmacokinetic and toxicity profiles, and as a result they were all progressed into Phase I clinical studies in 2009. Unfortunately, this first wave of selective c-Met inhibitors did not progress very far in the clinic. The subsequent failure of many of this first wave of c-Met inhibitors was a major setback, and subsequently led to a decline in research interest in the c-Met target.

However, we took the decline in interest as an opportunity to increase our investment in our selective c-Met research program. We studied emerging hypotheses around the reason for the kidney toxicity issues in the above mentioned c-Met inhibitors. The issue appeared to be that certain metabolites of earlier compounds had dramatically reduced solubility and appeared to crystalize in the kidney, resulting in obstructive toxicity. These metabolites were not evident in the pre-clinical animal models and only became evident in human testing.

During 2010 and 2011, we designed and completed pre-clinical studies for our compound, savolitinib (also known as AZD6094 and HMPL-504, formerly known as volitinib). Despite replacing the quinoline region of the earlier c-Met compounds which was believed to help drive their selective properties, savolitinib remains a highly selective compound. It also has the important advantage that it has not shown any renal toxicity to date and does not appear to carry the same metabolites problems as the earlier selective c-Met compounds.

Figure 2: Chemical structures of selective c-Met inhibitors versus savolitinib chemical structure, showing replacement of the quinoline group

#### Sources:

- 1. Zou H, et al, 99<sup>th</sup> Annual Meeting for American Association for Cancer Research (AACR); 12 16 April 2008; San Diego, USA
- 2. Perera T, et al, 99th Annual Meeting for American Association for Cancer Research (AACR); 12 16 April 2008; San Diego, USA
- 3. Bounaud et al, WO 2008/051808 A2
- 4. Liu X, et al, 99<sup>th</sup> Annual Meeting for American Association for Cancer Research (AACR); 12 16 April 2008; San Diego, USA
- 5. Su W, et al, 105th Annual Meeting of the American Association for Cancer Research (AACR); April 2014; San Diego, USA
- 6. Diamond S, et. al, Species-specific metabolism of SGX523 by aldehyde oxidase, Drug Metabolism and Disposition, 2010, 38, 1277-85

#### Savolitinib Pre-clinical Evidence

In vitro biological profile

In pre-clinical studies, savolitinib demonstrated strong in vitro activity against c-Met, affecting its downstream signaling targets and thus blocking the related cellular functions effectively, including proliferation, migration, invasion, scattering and the secretion of vascular endothelial growth factor, or VEGF, that plays a pivotal role in tumor angiogenesis.

One of our key areas of focus in our pre-clinical studies was to achieve superior selectivity of savolitinib on a number of kinases. A commonly used quantitative measure of selectivity is  $IC_{50}$ , which represents the concentration of a drug that is required for 50% inhibition of the target kinase in vitro and the plasma concentration required for obtaining 50% of a maximum effect in vivo. High selectivity is achieved with a very low  $IC_{50}$  for the target cells, and a very high  $IC_{50}$  for the healthy cells (approximately 100 times higher than for the target cells). In the c-Met enzymatic assay, which is a method of measuring enzyme activity, savolitinib showed potent activity with  $IC_{50}$  of 5 nM (nano-mole, a microscopic unit of measurement for the number of small molecules required to deliver the desired inhibitory effect). In a kinase selectivity screening with 274 kinases, savolitinib had potent activity against the c-Met Y1268T

mutant (comparable to the wild-type), weaker activity against other c-Met mutants and almost no activity against all other kinases. Savolitinib was found to be approximately 1,000 times more potent to c-Met than the next non-c-Met kinase.

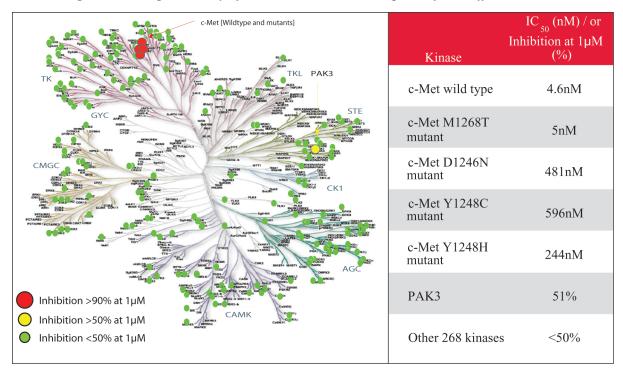


Figure 3: The high selectivity of savolitinib as shown on a panel of 274 different kinases

Source: W. Su, et al, 2014 American Association for Cancer Research

Note: The red dots shown in the graphic represent the five kinases, all c-Met wild-type or mutations, which are inhibited over 90% at 1,000 nM (1  $\mu$  M) of savolitinib. The other 269 kinases are inhibited by less than 51%.

In cell-based assays measuring activity against c-Met phosphorylation, savolitinib demonstrated potent activity in both ligand-independent (gene amplified) and ligand-dependent (over-expression) cells with  $IC_{50}s$  at low nanomolar levels. Phosphorylation is the binding of a phosphate group to a protein or other organic molecule, which has the effect of activating the function of that protein.

In target related tumor cell function assays, including inhibition on HGF-dependent tumor cell proliferation, migration, and invasion, savolitinib showed high potency with  $IC_{50}$  of less than 10 nM. In addition, savolitinib demonstrated potent in vitro anti-angiogenesis activity. Savolitinib inhibited VEGF secretion of lung cancer cell H441 in a dose-dependent manner with an  $IC_{50}$  of 45 nM and inhibited HGF-dependent human umbilical vein endothelial cells tube formation with an  $IC_{50}$  of 12 nM.

Furthermore, when we tested savolitinib in several different tumor cell lines, it demonstrated cytotoxicity only on tumor cells that were c-Met gene amplified or c-Met over-expressed. In other cells, inhibition measurements demonstrated that  $IC_{50}$  amounts were over 30,000 nM, which is thousands of times higher than the  $IC_{50}$  on c-Met tumor cells. For example, in testing savolitinib in NCI-H1993 non-small cell lung cancer cells, which have high c-Met gene amplification,  $IC_{50}$  measurements were less than 10 nM. This suggests that it would require at least 3,000 times as much savolitinib to inhibit non-c-Met cells to the same degree as it inhibits a NCI-H1993 c-Met cell, thereby demonstrating savolitinib's high selectivity for c-Met. Similarly, in c-Met gene amplified gastric cancer cells such as SNU-5 and Hs746T, savolitinib demonstrated  $IC_{50}$ s of 3 nM and 5 nM, respectively.

The data above suggest that (i) savolitinib has potent activity against tumor cell lines with c-Met gene amplification in the absence of HGF, indicating that there is HGF-independent c-Met activation in these cells; (ii) savolitinib has potent activity in tumor cell lines with c-Met over-expression, but only in the presence of HGF, indicating HGF-dependent c-Met activation; and (iii) savolitinib has no activity in tumor cell lines with low c-Met over-expression/gene amplification, suggesting that savolitinib has strong kinase selectivity.

#### In vivo efficacy

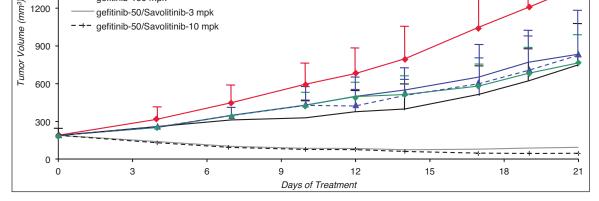
We tested the in vivo activity of savolitinib on different human tumor xenograft models (a common pre-clinical technique where human tumor cells are transplanted into various animal models). For example, in a gastric cancer Hs746T model with c-Met gene amplification, savolitinib was found to inhibit tumor growth potently with good dose response. At a 2.5 mg/kg (kg weight of the animal) once daily oral dose, savolitinib induced tumor shrinkage, suggesting potent anti-tumor activity. Moreover, the anti-tumor activity appeared to correlate well with the inhibition of c-Met phosphorylation and activation.

Similarly and as in the NCI-H1993 in vitro studies, in vivo studies on c-Met gene amplified NCI-H1993 xenografts also showed significant anti-tumor efficacy, with a median effective dose, or ED<sub>50</sub>, of 4.7 mg/kg per day. The median effective dose is the dose that produces the desired effect in 50% of the population that takes it.

Savolitinib showed strong synergistic effects with other anti-cancer therapies in certain pre-clinical models. We developed the HCC827C4R model to test several savolitinib combinations, a model which has high c-Met gene amplification and is originally derived from a non-small cell cancer cell line that is highly sensitive to EGFR inhibitors. The combination of savolitinib with the EGFR inhibitor Iressa in the HCC827C4R xenograft model demonstrated strong synergistic effect, suggesting targeting multiple pathways simultaneously may provide a viable approach for the treatment of tumors with activation of multiple pathways. These data suggest that there is a strong rationale for patients whose disease progressed after EGFR tyrosine kinase inhibitor treatment with c-Met gene amplification to use a combination therapy including savolitinib.

model to test several savolitinib (HMPL-504) combinations, showing a clear dose-dependent response 1800 Vehicle savolitinib-3 mpk savolitinib-10 mpk 1500 aefitinib-50 mpk gefitinib-100 mpk 1200 gefitinib-50/Savolitinib-3 mpk

Figure 4: Savolitinib in combination with Iressa in the HCC827C4R Met gene amplification



Source: Chi-Med pre-clinical data for savolitinib

Note: mpk = mg per kg of animal

We also studied in several subcutaneous xenograft models the anti-tumor effect of savolitinib in combination with Taxotere, a commonly used chemotherapy in gastric cancer treatment. In our studies, the combination produced additive or synergistic anti-tumor effect, and no significant additive or synergistic toxicity between the two drugs was found.

#### Savolitinib Early and Completed Clinical Development

As discussed below, we have completed various clinical trials of savolitinib in Australia and China.

Savolitinib Phase I study in Australia

We conducted the first-in-human Phase I study of savolitinib in patients with advanced solid tumors starting in 2012 in Australia. The study was conducted to determine the maximum tolerated dose or recommended Phase II dose, dose-limiting toxicities, pharmacokinetics profile and preliminary anti-tumor activity of savolitinib. The first patient was enrolled in February 2012, and enrollment of a total of 47 patients was completed in June 2015.

The data of 35 patients in the dose escalation stage of this Phase I study were presented at the 2014 annual meeting of the American Society of Clinical Oncology. CTC grade  $\geq 3$  adverse events with greater than 5% incidence associated with savolitinib treatment were fatigue (9.1%) and shortness of breath, or dyspnea (6.1%). Four patients reported five incidences of dose-limiting toxicities, including one CTC grade 3 incidence of elevated alanine transaminase (600 mg once daily), one incidence of CTC grade 3 fatigue (800 mg once daily), two incidences of CTC grade 3 fatigue and one incidence of CTC grade 3 headache (1,000 mg once daily). Notably, no obstructive kidney toxicity was seen in this study.

We identified 800 mg as the maximum tolerated dose of the once daily regimen. A pharmacokinetics analysis showed savolitinib was rapidly absorbed with a half-life of approximately five hours, and drug exposure increased in a dose-proportional manner and with no obvious accumulation. This study showed that savolitinib was well tolerated at doses of up to 800 mg once daily, proving that savolitinib is capable of providing complete target inhibition over 24 hours based on drug concentration required for complete c-Met phosphorylation inhibition derived in pre-clinical studies.

Savolitinib Phase I study in China

In June 2013, we initiated a Phase I dose escalation study of savolitinib in China. By June 2015, a total of 41 patients had been enrolled across the dose escalation and dose expansion stages of the study. We concluded that the data from this China Phase I study were consistent with the Australian Phase I study discussed above and that savolitinib was well tolerated at doses up to 800 mg once daily or 600 mg twice daily. The complete Phase I study results, combining data from Australia and China, were presented at the American Society of Clinical Oncology's annual meeting in 2015.

#### Kidney Cancer

Emerging Efficacy in Papillary Renal Cell Carcinoma

During the Australia Phase I study, our investigators began to notice positive outcomes among papillary renal cell carcinoma patients with a strong correlation to c-Met gene amplification status. As a result, we became interested in this area because there are no effective approved treatments to date for papillary renal cell carcinoma.

Out of a total of eight papillary renal cell carcinoma patients in our Australia Phase I study who have been treated with various doses of savolitinib, three have achieved confirmed partial response (tumor measurement reduction of greater than 30%). One of these patients has been on the drug for over 30 months and has had tumor measurement reduction of greater than 85%. A further three of these eight

papillary renal cell carcinoma patients achieved stable disease, which means patients without partial response but with a tumor measurement increase of less than 20%.

The aggregate objective response rate (the percentage of patients in the study who show either partial response or complete response) of 38% is very encouraging for papillary renal cell carcinoma, which as stated above currently has no effective approved treatments on the global market. These responses were also durable as demonstrated by a patient who has been on the therapy for over 30 months. Prior to savolitinib, the highest objective response rate reported for a papillary renal cell carcinoma specific Phase II study (of 74 papillary renal cell carcinoma patients) was 13.5% by foretinib (a multi-kinase inhibitor of c-Met/VEGFR2, which was not submitted for regulatory approval) in 2012, as reported by the National Institutes of Health's National Center for Biotechnology Information.

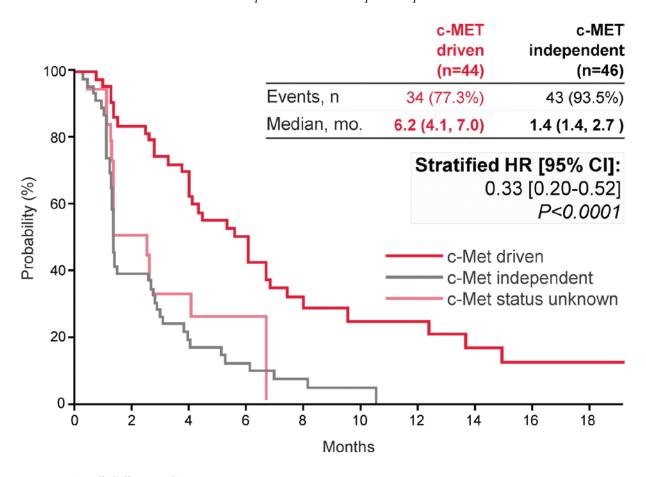
Importantly, the level of tumor response among these papillary renal cell carcinoma patients correlated closely with the level of c-Met gene amplification. The patients with consistent c-Met gene amplification (across the whole tumor) respond most to savolitinib. Patients with c-Met gene amplification on parts of the tumor (focal Met) respond only if it is a large part of the tumor. Finally, patients with no c-Met gene amplification respond least. Importantly, the magnitude of c-Met gene amplification can vary widely between patients, with those patients with the highest level of c-Met gene amplification responding most to the treatment.

In addition, a colorectal cancer patient in the Phase I study with high levels of c-Met gene amplification in the 600 mg once daily cohort achieved 29% tumor reduction.

Phase II study of savolitinib monotherapy in papillary renal cell carcinoma in the United States, Canada and Europe

In early 2017, we presented the results of our 109-patient global Phase II study in papillary renal cell carcinoma at the American Society of Clinical Oncology Genitourinary Cancers Symposium as well as in the Journal of Clinical Oncology as a Rapid Communication Manuscript. This Phase II study was the largest and most comprehensive clinical study in papillary renal cell carcinoma ever conducted. Of 109 patients treated with savolitinib, papillary renal cell carcinoma was c-Met driven in 44 patients (40%), c-Met independent in 46 patients (42%) and Met status unknown in 19 patients (17%). c-Met driven papillary renal cell carcinoma was strongly associated with encouragingly durable response to savolitinib with an objective response rate in the c-Met driven group of 18.2% (8/44) as compared to 0% (0/46) in the c-Met independent group (p=0.002), based on confirmed partial responses. Median progression-free survival for patients with c-Met driven and c-Met independent papillary renal cell carcinoma patients was 6.2 months (95% confidence interval: 4.1-7.0) and 1.4 months (95% confidence interval: 1.4-2.7), respectively (hazard ratio=0.33; 95% confidence interval: 0.20-0.52; log-rank p<0.0001). Savolitinib was well tolerated, with no reported treatment related CTC grade ≥3 adverse events with greater than 5% incidence. Total aggregate savolitinib treatment-related CTC grade ≥3 adverse events occurred in just 19% of patients comparing very well to the 70-75% CTC grade ≥3 adverse event level recorded in VEGFR inhibitors such as Sutent and Votrient (pazopanib) in multiple renal cell carcinoma studies (N Eng J Med 369;8, R J Motzer et al).

Figure 5: Phase II study of savolitinib monotherapy in papillary renal cell carcinoma in the United States, Canada and Europe. This study clearly demonstrated c-Met driven patients had better progression-free survival compared to c-Met independent patients.



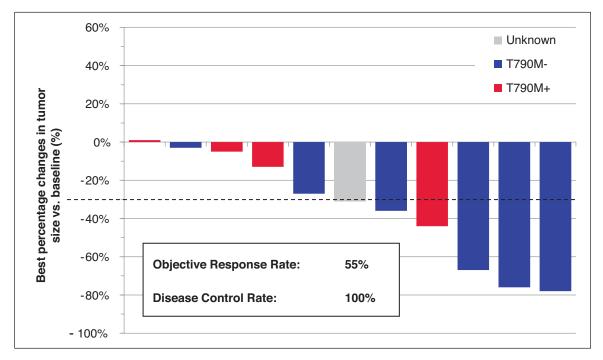
### Non-Small Cell Lung Cancer

Phase I study of savolitinib in combination with Tagrisso T790M(+/-) non-small cell lung cancer (AstraZeneca TATTON (Part A) dose finding study)

In November 2015, AstraZeneca received FDA approval for Tagrisso, its drug candidate for the treatment of T790M+ EGFRm+, tyrosine kinase inhibitor-resistant non-small cell lung cancer. Tagrisso was granted Breakthrough Therapy designation and expedited approval by the FDA and was one of the fastest development programs ever recorded at just over two and a half years from the start of Phase I clinical trials to FDA approval. We understand that the speed of development and approval of Tagrisso was driven by the clearly defined molecular pathways (T790M), the existence of a major unmet medical need in the treatment of non-small cell lung cancer, and the high degree of efficacy demonstrated by Tagrisso. In this T790M+ patient population, Tagrisso recorded an objective response rate of 59% in two large-scale Phase II studies that formed the basis for FDA approval. Another portion of EGFRm+ tyrosine kinase inhibitor-resistant patients progresses because of c-Met gene amplification. The TATTON (Part A) Phase I study of Tagrisso plus savolitinib combination treatment was initiated in August 2014 to determine the safety and tolerability of the combination therapy and the recommended Phase II dose. Based on the positive safety and tolerability results and encouraging early clinical efficacy, a TATTON (Part B) Phase IIb proof-of-concept study was initiated to confirm safety and efficacy.

The primary objective of the TATTON Phase I (Part A) study was to establish a safe and effective combination dose. All patients were screened for their T790M status (+/-) as well as some for their c-Met gene amplification status, if sufficient tissue samples were available, although patients of all tumor types were admitted to the trial regardless of status. A total of 12 patients were dosed with either 600 mg or 800 mg of savolitinib in combination with 80 mg of Tagrisso once daily. It was found that both 600 mg and 800 mg once daily could be combined with 80 mg of Tagrisso once daily with a safety profile consistent with single agent use. Furthermore, of the 11 evaluable patients in the study, six confirmed partial responses have been observed to date. This resulted in an objective response rate of 55% and contributed to a disease control rate of 100%.

Figure 6: Best percentage changes in tumor size versus baseline in patients (with each column representing a single patient) treated with a combination of savolitinib and Tagrisso in the TATTON Phase I (Part A) study, by T790M status when available



Source: Oxnard et al, Preliminary results of TATTON (Part A), a multi-arm Phase I trial of AZD9291 combined with MEDI4736, AZD6094 or selumetinib in EGFR-mutant lung cancer, J Clin Oncol 33, 2015 (suppl; abstr 2509)

Note: 6 patients ongoing treatment at data cut-off

None of the adverse effects in the 600 mg dose were CTC grade  $\geq 3$ , and only two in the 800 mg dose were CTC grade  $\geq 3$ . These were nausea (8.3%) and decreased white blood cell count (8.3%).

This novel combination of two well-tolerated therapies, albeit on a low base size, has delivered significant objective response rate levels. As a result, we have expanded the TATTON Phase Ib study to demonstrate broader proof-of-concept, as discussed below in Target Patient Population 6 in the pipeline chart.

### Savolitinib Current Clinical Development and Near-Term Plans

We are currently testing savolitinib in partnership with AstraZeneca in multiple Phase Ib/II studies, both as a monotherapy and in combination with other targeted therapies. In June 2017, we initiated our

first global Phase III registration study in papillary renal cell carcinoma. In late 2017, we presented positive Phase Ib/II data at the World Conference on Lung Cancer on savolitinib in combination with Tagrisso and Iressa, in both second- and third-line non-small cell lung cancer and are now working closely with AstraZeneca on next steps for development as discussed below.

### Kidney Cancer

Phase III papillary renal cell carcinoma, savolitinib (600 mg once daily) monotherapy—Global (Target Patient Population 1 in pipeline chart; Status: enrolling; NCT03091192)

Papillary renal cell carcinoma is the most common of the non-clear cell renal cell carcinomas representing about 14% of kidney cancer. Approximately 366,000 new cases of kidney cancer were diagnosed globally in 2015, equating to about 50,000 cases of papillary renal cell carcinoma, with approximately half harboring c-Met driven disease. No targeted therapies have been approved specifically for papillary renal cell carcinoma, and to date only modest efficacy in non-clear cell renal cell carcinoma has been reported in sub-group analyses of broader renal cell carcinoma studies of VEGFR (e.g., Sutent) and mammalian target of rapamycin (e.g., Afinitor) tyrosine kinase inhibitors, with objective response rates of <10% and median progression-free survival in first-line setting of four to six months and second-line setting of only one to three months (ESPN study, Tannir N. M. et al.).

Based on the Phase II results we presented in early 2017, we initiated the SAVOIR study in June 2017. The SAVOIR study is a global Phase III, open-label, randomized, controlled trial evaluating the efficacy and safety of savolitinib, compared with sunitinib, in patients with c-Met driven, unresectable, locally advanced or metastatic papillary renal cell carcinoma. C-Met status is confirmed by the novel targeted next-generation sequencing assay developed for savolitinib. Patients will be randomized in a 1:1 ratio to receive either continuous treatment with savolitinib 600 mg (400 mg if <50 kg) orally, once daily, or intermittent treatment with sunitinib 50 mg orally once daily (four weeks on/two weeks off), on a six-week cycle. The primary endpoint for efficacy in the SAVOIR study is median progression-free survival, with secondary endpoints of overall survival, objective response rate, duration of response, best percentage change in tumor size, disease control rate, and safety and tolerability. We expect to complete enrollment in late 2019.

Furthermore, in order to fully understand the role of c-Met driven disease in papillary renal cell carcinoma, we are currently conducting a global molecular epidemiology study. The molecular epidemiology study is in the process of screening, using our companion diagnostic, archived tissue samples from over 300 papillary renal cell carcinoma patients to identify c-Met driven disease. Historical medical records from these patients will then be used to determine if c-Met driven disease is predictive of worse outcome, in terms of progression-free survival and overall survival, in papillary renal cell carcinoma patients. If this is proven to be the case, we will consider engaging in discussions regarding Breakthrough Therapy potential with the U.S. FDA.

Phase II study of multiple tyrosine kinase inhibitors in metastatic papillary renal cell carcinoma— United States (Target Patient Population 2 in pipeline chart; Status: enrolling; NCT02761057)

A Phase II study, sponsored by the U.S. National Cancer Institute, and named the PAPMET study, to assess the efficacy of multiple tyrosine kinase inhibitors in metastatic papillary renal cell carcinoma patients including Sutent, Cabometyx (cabozantinib), Xalkori (crizotinib) and savolitinib. PAPMET began enrolling patients in 2016. The PAPMET study is expected to enroll about 180 patients in over 70 locations in the United States with top-line data targeted for reporting in 2019.

Phase II study of savolitinib (600 mg once daily) monotherapy and in combination with Imfinzi (anti-programmed death-ligand 1) in both papillary renal cell carcinoma and clear cell renal cell carcinoma patients—U.K./Spain (Target Patient Populations 3, 4 and 5 in pipeline chart; Status: enrolling; NCT02819596)

The CALYPSO study, a dose finding study to assess safety/tolerability of savolitinib and Imfinzi combination therapy as well as preliminary efficacy of savolitinib as a monotherapy or combination therapy in several c-Met driven kidney cancer patient populations, began at St. Bartholomew's Hospital in London in 2016. In 2016, the dose-finding phase of the CALYPSO study successfully established the combination dose of savolitinib and Imfinzi and the study moved on to the Phase II expansion stage in papillary renal cell carcinoma and clear cell renal cell carcinoma patients in the United Kingdom and Spain to further explore efficacy in 2017.

### Non-small Cell Lung Cancer

Phase Ib/II expansion non-small cell lung cancer (second-line), EGFR tyrosine kinase inhibitor-refractory, savolitinib (600 mg once daily) in combination with Tagrisso—Global (Target Patient Population 6 in pipeline chart; Status: enrolling; NCT02143466)

In October 2016, at the European Society for Medical Oncology meeting, AstraZeneca presented preliminary proof-of-concept data from the TATTON study (Part A) on 17 evaluable first-generation EGFR tyrosine kinase inhibitor (Iressa/Tarceva) refractory second-line non-small cell lung cancer patients who had no prior exposure to third-generation EGFR tyrosine kinase inhibitors (Tagrisso/rocelitinib). Molecular analysis of both c-Met and T790M status was completed for patients with sufficient available tumor tissue. Of patients treated with the savolitinib and Tagrisso combination, confirmed partial responses were reported in 4/5 (80% objective response rate) c-Met positive/T790M negative patients and in 6/10 (60% objective response rate) c-Met positive patients regardless of T790M status.

In 2016, we initiated a global Phase Ib/II expansion study in second-line non-small cell lung cancer, called the TATTON study (Part B), aiming to recruit sufficient c-Met gene amplified patients who had progressed after prior treatment with a first-generation EGFR inhibitor (Iressa/Tarceva) to support a decision on global Phase II/III registration strategy. In this first-generation EGFR tyrosine kinase inhibitor refractory non-small cell lung cancer population, we estimate that c-Met gene amplification occurs in 15-20% of patients. Preliminary data from TATTON (Part B), in 34 evaluable patients, were presented at the 2017 World Conference on Lung Cancer and showed confirmed partial responses in 14/23 (61% objective response rate) of T790M mutation negative patients, as well as confirmed partial responses in 6/11 (55% objective response rate) of T790M mutation positive patients. AstraZeneca has recently decided to progress into the next stage of development in this indication, with plans outlined below.

Figure 7: Preliminary data from TATTON study (Part B) were compelling and consistent with the TATTON study (Part A)

<b>TATTON A</b>		TATTON B – in MET+ EGFRi failure patients					
MET testing confirmation	Objective response rate, n (%)	Total (n = 10)	MET testing confirmation	Objective response rate, n (%)	MET+/ T790M+ (n = 11)	MET+ (T790M-) (n = 23)	Total (n = 34)
	Confirmed Partial Response	6 (60%)	Local or Central	Confirmed Partial Response	6 (55%)	14 (61%)	20 (59%)
					(n = 7)	(n = 15)	(n = 22)
Local or Central			Central*	Confirmed Partial Response	4 (57%)	8 (53%)	12 (55%)
				Stable Disease ≥6 weeks	3 (43%)	6 (40%)	9 (41%)
				Progressive Disease/death	0	1 (7%)	1 (5%)
				Not Evaluable	0	0	0 (0)
				DoR, months (range)	9.7 (2.8*-9.7)	NR (1.6*-5.9*)	NR (1.6*-9.7)
Best % change from baseline in tumor lesion size in							

Note: \*Centrally confirmed MET-amplification (fluorescence in-situ hybridization, MET gene copy ≥5 or MET/CEP7 ratio ≥2)

Phase Ib/II non-small cell lung cancer (third-line), EGFR/T790M tyrosine kinase inhibitor-refractory, savolitinib (600 mg once daily) in combination with Tagrisso—Global (Target Patient Population 7 in pipeline chart; Status: enrolling; NCT02143466)

The TATTON study (Part B) also enrolled third-line non-small cell lung cancer patients that had progressed after treatment with Tagrisso as a result of c-Met gene amplification acquired resistance. Data presented in June 2017 at the American Society of Clinical Oncology, by Harvard Medical School and Massachusetts General Hospital Cancer Center showed that about 30% (7/23 patients) of Tagrissoresistant third-line non-small cell lung cancer patients harbor c-Met gene amplification. This third-line patient population is generally heavily pre-treated and highly complex from a molecular analysis standpoint, with the study showing that more than half of the c-Met gene amplification patients also harbored additional genetic alterations, including but not limited to, EGFR gene amplification and K-Ras mutations.

The TATTON (Part B) study, presented at the 2017 World Conference on Lung Cancer, also included preliminary data in 30 evaluable patients previously treated with third-generation T790M-directed EGFR inhibitors, primarily Tagrisso. Confirmed partial responses were observed in 10/30 (33% objective response

rate) of these patients, and while this is lower than the 55-61% objective response rate in Target Patient Population 6, it was as expected given the additional driver genes at work post-Tagrisso monotherapy failure. We believe that the savolitinib/Tagrisso combination is an important treatment option for these late-stage patients who have no remaining targeted treatment alternatives.

Tagrisso sales in 2017, only the second year since its launch, were \$955 million. At current pricing, this would indicate that over 5,000 patients were treated with Tagrisso during 2017, thereby indicating that the market potential for savolitinib in third-line, Tagrisso resistant, non-small cell lung cancer could be material.

Figure 8: The savolitinib/Tagrisso combination could be an important treatment option for the third-line or above non-small cell lung cancer patients who have no remaining targeted treatment alternatives

#### TATTON B – in MET+ Tagrisso failure patients . T790M directed EGFR-TKI MET+ (n = 30) MET testing confirmation Objective response rate, n (%) Local or Central\* Confirmed PR 10 (33%) 100 (n = 25)80 Confirmed PR 7 (28%) Best % change from baseline in tumor lesion size SD ≥6 weeks 13 (52%) 60 PD/death 4 (16%) Central' 1 (4%) 40 DoR, months (range) NR (2.2\*-9.6\*) Centrally confirmed MET-amplification (fluorescence in-situ hybridization, MET gene copy ≥5 or MET/CEP7 ratio ≥2). 20 0 -20 -80 -100

Note: \*Centrally confirmed MET-amplification (fluorescence in-situ hybridization, MET gene copy ≥5 or MET/CEP7 ratio ≥2)

AstraZeneca decision on further development in Target Patient Populations 6 and 7

In December 2017, AstraZeneca's governance committee in oncology reviewed the TATTON (Part B) data that had been presented at the 2017 World Conference on Lung Cancer, to decide strategy for further development of the savolitinib and Tagrisso combination in first-generation (Iressa/Tarceva) and third-generation (Tagrisso) EGFR-tyrosine kinase inhibitor refractory non-small cell lung cancer.

At that time, while the above strong objective response rate data was available for the savolitinib (600 mg once daily) plus Tagrisso (80 mg once daily) combination dose regimen, neither median progression-free survival nor duration of response had been reached. Since then, both progression-free survival and duration of response have continued to mature. The safety profile of the combination is in line with previous reports for savolitinib (600 mg once daily) plus Tagrisso (80 mg once daily) and going forward, AstraZeneca has concluded that a weight-based dosing algorithm will be applied for the combination, similar to the dosing algorithm used in the SAVOIR Phase III study in papillary renal cell carcinoma.

Encouraged by the TATTON (Part B) data, AstraZeneca has decided to proceed with development in second-line non-small cell lung cancer (Target Patient Population 6 in the pipeline chart). Planning is now underway to initiate a global randomized chemotherapy-doublet (platinum plus Alimta) controlled study of the savolitinib plus Tagrisso combination in first-generation (Iressa/Tarceva) EGFR-tyrosine kinase inhibitor refractory, c-Met driven and T790M negative non-small cell lung cancer patients. This second-line non-small cell lung cancer study, currently targeted to start in the second half of 2018, will start as a Phase II study until such time that regulatory discussions have taken place on dosing approach, and will be powered based on TATTON (Part B) for objective response rate and progression-free survival.

To further support dosing approach ahead of regulatory discussions, AstraZeneca has already initiated TATTON (Part D), exploring savolitinib (300 mg once daily) dose combined with Tagrisso (80 mg once daily), to explore the lower dose in the context of maximizing tolerability of the combination for patients who could be on the combination for long periods of time. A second supporting study, a Phase II, aiming at strengthening the dose justification in EGFR-tyrosine kinase inhibitor refractory, c-Met driven non-small cell lung cancer will also start in the second half of 2018, randomizing to either 300 mg savolitinib once daily plus Tagrisso (80 mg once daily) or 600 mg savolitinib (with weight-based dosing) once daily plus Tagrisso (80 mg once daily) with a primary endpoint of tolerability.

Late in 2018 or early in 2019, and subject to the outcome of the mature TATTON (Part B) data as well as preliminary TATTON (Part D) results, we expect AstraZeneca to engage in regulatory discussions regarding our dosing approach for the savolitinib and Tagrisso combination as well as potential Breakthrough Therapy. These regulatory discussions will also enable AstraZeneca to decide development strategy in third-line non-small cell lung cancer (Target Patient Population 7 in the pipeline chart), defined as third-generation (Tagrisso) EGFR-tyrosine kinase inhibitor refractory, c-Met gene amplified non-small cell lung cancer patients.

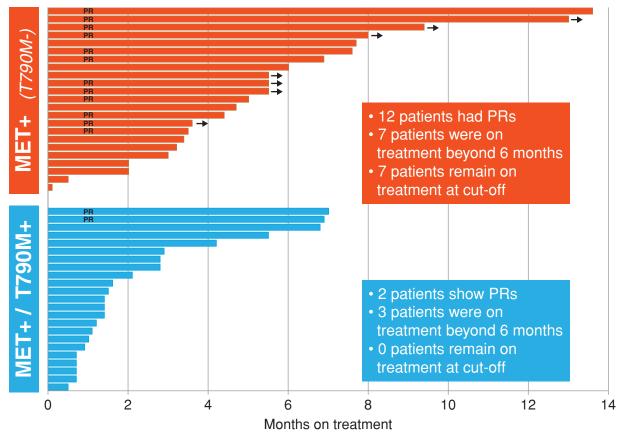
Phase II non-small cell lung cancer (second-line), EGFR tyrosine kinase inhibitor-refractory, savolitinib (600 mg once daily) in combination with Iressa—China (Target Patient Population 8 in pipeline chart; Status: completed; NCT02374645)

At the 2017 World Conference on Lung Cancer, we presented Phase II proof-of-concept data assessing savolitinib in combination with Iressa in patients in China with EGFRm+ advanced non-small cell lung cancer with centrally confirmed c-Met gene amplification who had progressed following first-generation EGFR inhibitor therapy. Preliminary results showed confirmed partial responses in 12/23 (52% objective response rate) of T790M mutation negative patients, as well as confirmed partial responses in 2/23 (9% objective response rate) of T790M mutation positive patients. The 52% objective response rate in T790M mutation negative patients was as expected and similar to that recorded in TATTON (Part B) for this target patient population, indicating that for these patients Iressa might be the most cost-efficient combination partner for savolitinib. The low 9% objective response rate in T790M mutation positive patients was also as expected, as Iressa does not effectively address T790M mutants. In terms of safety, the savolitinib plus Iressa combination dose was safe and well tolerated.

With the launch of multiple lower-priced and reimbursed generic first-generation EGFR tyrosine kinase inhibitors in China in 2017, combined with the approximately 50% proportion of non-small cell lung cancer patients who harbor the EGFRm+, we believe there may be a surge in c-Met gene amplified second-line non-small cell lung cancer patients in China over the coming years. We continue to discuss Phase III plans in this target patient population for the savolitinib/Iressa combination in China with AstraZeneca and expect to reach agreement in 2018.

Figure 9: The savolitinib/Iressa combination has demonstrated strong and durable response in Met+ (T790M-) patients

MET testing confirmation	Objective response rate, n (%)	MET+ / T790M+ (n = 23)	MET+ ( <i>T790M-</i> ) (n = 23)	MET+ / T790M unknown (n = 5)	Total (n = 51)
Central	<b>Confirmed partial response</b>	2 (9%)	12 (52%)	2 (40%)	16 (31%)
	Stable disease ≥6 weeks	9 (39%)	7 (30%)	2 (40%)	18 (35%)
	Progressive disease/death	7 (30%)	3 (13%)	0	10 (20%)
	Not evaluable	5 (22%)	1 (4%)	1 (20%)	7 (14%)



Note:

1. Cut-off as of August 21, 2017

Phase II c-Met driven non-small cell lung cancer, savolitinib (600 mg once daily) monotherapy—China (Target Patient Populations 9 and 10 in pipeline chart; Status: enrolling; NCT01935555/NCT02897479)

Phase II studies of savolitinib are also ongoing in non-small cell lung cancer and other lung cancer patient populations, focusing on those with c-Met driven disease.

#### Gastric Cancer

Phase II gastric cancer studies are ongoing in China as well as the Phase II VIKTORY study, being conducted at Samsung Medical Center in South Korea, in which savolitinib is represented in two out of the

ten treatment arms. As of the latest report in 2017, a total of over 850 gastric cancer patients have been screened in these studies and those patients with confirmed c-Met driven disease are being treated with either savolitinib monotherapy or savolitinib in combination with Taxotere. Presentations of preliminary data from these studies were made in 2017 at the Chinese Society of Clinical Oncology (China Phase II) and the American Society of Clinical Oncology (VIKTORY Phase II).

In China as of June 2017, a total of 441 metastatic gastric cancer patients had been screened with 13.2% (58/441) determined to have aberrant c-Met, of which 5.3% (23/438) were c-Met gene amplified. A total of 31 patients in China have been enrolled to date in Target Patient Population 11 in the pipeline chart as discussed below. In South Korea as of January 2017, a total of 438 metastatic gastric cancer patients had been screened with 5.3% (23/438) being patients with c-Met driven (gene amplification or over-expression) disease. A total of 23 patients in South Korea have been enrolled to date in Target Patient Populations 11, 12 and 13 in the pipeline chart as discussed below.

Phase Ib gastric cancer, savolitinib monotherapy, patients with c-Met gene amplification—China and South Korea (Target Patient Population 11 in pipeline chart; Status: enrolling; NCT01985555/NCT02449551)

Preliminary results were presented at the 2017 Chinese Society of Clinical Oncology for the efficacy evaluable c-Met gene amplified patients in China. Based on confirmed and unconfirmed partial responses, the objective response rate was 42.9% (3/7) and disease control rate was 85.7% (6/7), with objective response rate of 13.6% (3/22) and disease control rate of 40.9% (9/22) among the overall efficacy evaluable aberrant c-Met set. As of data cut-off, the longest duration of treatment was in excess of two years. Savolitinib monotherapy was determined to be safe and well tolerated in patients with advanced gastric cancer. CTC grade  $\geq 3$  treatment emergent adverse events with greater than 5% incidence included abnormal hepatic function in 12.9% (4/31), gastrointestinal bleeding or decreased appetite in 9.7% (3/31 each), and diarrhea or gastrointestinal perforation in 6.4% (2/31 each). This China study concluded that savolitinib monotherapy demonstrated promising anti-tumor efficacy in gastric cancer patients with c-Met gene amplification. We believe the potential benefit to these patients warrants further exploration, with Phase II enrollment continuing in China. The VIKTORY Phase II study is ongoing in c-Met gene amplified patients in South Korea, with preliminary data likely to be presented at a major scientific conference in 2018.

Phase II gastric cancer, savolitinib (600 mg once daily) in combination with Taxotere in c-Met over-expression or c-Met gene amplification—South Korea (Target Patient Populations 12 and 13 in pipeline chart; Status: enrolling; NCT02447380/NCT02447406)

Phase II studies are underway to assess safety/tolerability of savolitinib and Taxotere combination as well as preliminary efficacy of the combination therapy in both c-Met gene amplified patients and the approximately 40% of gastric cancer patients that harbor c-Met over-expression. The VIKTORY Phase II study is ongoing in South Korea in Target Patient Populations 12 and 13, with preliminary data likely to be presented at a major scientific conference in 2018.

Phase II metastatic castration-resistant prostate cancer, savolitinib monotherapy—Canada (Target Patient Populations 14 in pipeline chart; Status: enrolling; NCT03385655)

A Phase II study is sponsored by the Canadian Cancer Trials Group to determine the effect of savolitinib on prostate-specific antigen decline and time to prostate-specific antigen progression. The study will assess the objective response rate as determined by RECIST 1.1 criteria, evaluate the safety and toxicity profile of savolitinib in metastatic castration-resistant prostate cancer patients and identify potential predictive and prognostic factors. The umbrella study targets to enroll around 500 patients into six treatment arms based on molecular status, with patients with c-Met-driven disease receiving savolitinib. High levels of c-Met over expression can be prevalent in prostate cancer patients.

#### Partnership with AstraZeneca

In December 2011, we entered into a global licensing, co-development, and commercialization agreement for savolitinib with AstraZeneca. Given the complexity of many of the signal transduction pathways and resistance mechanisms in oncology, the industry is increasingly studying combinations of targeted therapies (tyrosine kinase inhibitors, monoclonal antibodies and immunotherapies) and chemotherapy as potentially the best approach to treating this complex and constantly mutating disease. Based on savolitinib showing early clinical benefit as a highly selective c-Met inhibitor in a number of cancers, in August 2016 we and AstraZeneca amended our global licensing, co-development, and commercialization agreement for savolitinib. We believe that AstraZeneca's portfolio of proprietary targeted therapies is well suited to be used in combinations with savolitinib, and we are studying combinations with Iressa (EGFRm+), Tagrisso (T790M+) and anti-programmed death-ligand 1 antibody Imfinzi. These combinations of multiple global first-in-class compounds are difficult to replicate, and we believe represent a significant opportunity for us and AstraZeneca.

For more information regarding our partnership with AstraZeneca, see "—Overview of Our Collaborations."

### Fruquintinib VEGFR 1, 2 and 3 Inhibitor

When we established our medicinal chemistry research platform in 2005, our first priority area of interest was to discover drug candidates to overcome the shortcomings of a few drugs or drug candidates that were in late-stage clinical development at the time, but had a well understood mechanism of action. As a result, we developed fruquintinib (also known as HMPL-013), a VEGFR inhibitor that we believe is highly differentiated due to its superior kinase selectivity compared to other small molecule VEGFR inhibitors, which can be prone to excessive off-target toxicities. Fruquintinib only inhibits VEGFR1, 2 and 3, resulting in fewer off-target toxicities, thereby allowing for better target coverage, as well as possible use in combination with other agents such as chemotherapies, targeted therapies and immunotherapies.

We believe these are meaningful points of differentiation compared to other approved small molecule VEGFR inhibitors such as Sutent, Nexavar and Stivarga, and can potentially significantly expand the use and market potential of fruquintinib. Consequently, we believe that fruquintinib has the potential to become the global best-in-class small molecule VEGFR inhibitor for many types of solid tumors.

### **Mechanism of Action**

During the pathogenesis of cancer, tumors at an advanced stage can secrete large amounts of VEGF, a protein ligand, to stimulate formation of excessive vasculature (angiogenesis) around the tumor in order to provide greater blood flow, oxygen, and nutrients to fuel the rapid growth of the tumor. Since essentially all solid tumors require angiogenesis to progress beyond a few millimeters in diameter, anti-angiogenesis drugs have demonstrated benefits in a wide variety of tumor types. VEGF and other ligands can bind to three VEGF receptors, VEGFR1, 2 and 3, each of which has been shown to play a role in angiogenesis. Therefore, inhibition of the VEGF/VEGFR signaling pathway can act to stop the growth of the vasculature around the tumor and thereby starve the tumor of the nutrients and oxygen it needs to grow rapidly.

This therapeutic strategy has been well validated with several first-generation VEGF inhibitors having been approved globally since 2005 and 2006. These include both small molecule tyrosine kinase inhibitor drugs such as Nexavar and Sutent as well as monoclonal antibodies such as Avastin (bevacizumab). The success of these drugs validated VEGFR inhibition as a new class of therapy for the treatment of cancer.

### Fruquintinib Pre-clinical Evidence

Potency and Selectivity

Pre-clinical studies have demonstrated that fruquintinib is a highly selective VEGFR inhibitor with high potency and low cell toxicity at the enzymatic and cellular levels. Fruquintinib has been studied in nude mice models bearing various human tumors and has shown significant inhibition of tumor growth, with human gastric cancer showing the strongest sensitivity. A daily dose of 2 mg/kg was found to almost completely inhibit tumor growth in mice models.

As a result of off-target side effects, existing VEGFR inhibitors are often unable to be dosed high enough to completely inhibit VEGFR, the intended target. In addition, the complex off-target toxicities resulting from inhibition of multiple signaling pathways are often difficult to be managed in clinical practice. Combining such drugs with chemotherapy can lead to severe toxicities that can cause more harm than benefit to patients. To date, the first generation VEGFR tyrosine kinase inhibitors are rarely used in combination with other therapies, thereby limiting their potential. Because of the potency and selectivity of fruquintinib, we believe that it has the potential to be safely combined with other anti-cancer drugs, which could significantly expand its clinical potential.

The pharmacokinetic properties of fruquintinib in patients have also been found to have high drug exposures at the optimal 5 mg daily dose of approximately 6,000 h\*ng/mL (i.e., hours multiplied by nanogram per milliliter, which is a measurement of drug exposure over time), well above the exposure of 898 h\*ng/mL required to cover the VEGFR target to EC<sub>50</sub> levels in mouse models, suggesting potentially strong target coverage in humans at this dose. At this dose, we expect fruquintinib to fully inhibit VEGFR for an entire day through a single oral dose based on modeling using pre-clinical data. In contrast, Sutent achieved a drug exposure of only 592 h\*ng/mL at the maximum tolerated dose of 50 mg per day, which is well below the drug exposures required for target inhibition determined in its pre-clinical models of 2,058 h\*ng/mL, suggesting insufficient target coverage in humans.

### Fruquintinib Early and Completed Clinical Development

As discussed below, we have completed various clinical trials of fruquintinib in China.

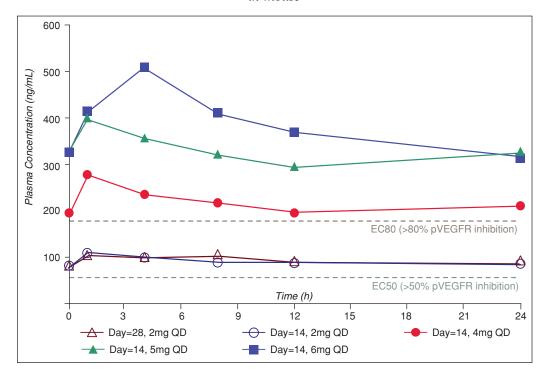
Phase I dose escalation study in patients with advanced solid tumors in China

This study was initiated in January 2011, and results were presented at the American Association for Cancer Research's meeting in 2013 and subsequently published in Cancer Chemotherapy and Pharmacology in August 2016. A total of 40 subjects with advanced solid tumors were enrolled in this clinical study. The primary endpoint was evaluation of safety during the first 28-day cycle of therapy following the initiation of multiple dosing of fruquintinib. The safety variables evaluated in this study were adverse events, physical examinations, vital signs (specifically including blood pressure), clinical laboratory evaluations including serum chemistry, hematology, urinalysis (with detailed sediment analysis, proteinuria, and 24-hour urine for collection of protein), and electrocardiograms.

Most adverse events were considered mild and graded as CTC grade 1 or 2. Adverse events CTC grade  $\geq 3$  with greater than 5% incidence related to fruquintinib treatment were hypertension (17.5%), hand-foot syndrome (17.5%), thrombocytopenia (12.5%), diarrhea (7.5%), fatigue (7.5%) and proteinuria (5.0%).

Furthermore, the Phase I study validated in humans the pre-clinical pharmacokinetic animal model findings of fruquintinib's ability to provide strong target coverage. The chart below shows that fruquintinib fully inhibits VEGFR in humans for the entire day at the optimal 5 mg daily dose level.

Figure 10: Fruquintinib plasma concentration in humans following once daily dosing in comparison to effective concentrations (EC) of fruquintinib required for VEGFR2 phosphorylation (activation) inhibition in mouse



Source: Chi-Med Phase I study data for fruquintinib

Note:  $EC_{50}$  = concentration of a drug that gives 50% of maximal response; EC80 = concentration of a drug that gives 80% of maximal response

Tumor response and progression were evaluated using the Response Evaluation Criteria in Solid Tumors version 1.0. In terms of efficacy, in the entire intent-to-treat population of 40 subjects, 14 had confirmed partial response, 14 had stable disease, six had progressed disease, and six were not evaluable. The objective response rate was 41% in the 34 evaluable patients and 35% in the entire intent-to-treat population of 40 patients, and the disease control rate was 82% among evaluable patients and 70% in the intent-to-treat population. Out of the 34 evaluable patients, only six patients had tumor growth, with the rest experiencing substantial tumor shrinkage.

In this Phase I study, clear tumor response was observed in multiple tumor types, consistent with the fact that angiogenesis, driven by VEGFR activation, accelerates the growth of tumors in many settings. The highest objective response rate in this Phase I study was achieved in non-small cell lung cancer and gastric cancer patients with objective response rates of over 50%. However, we also observed objective response rates of approximately 30% in colorectal and breast cancer patients.

As a result of this study, we determined that either 4 mg once daily or 5 mg once daily on a 3-weeks-on/1-week-off basis was safe and tolerable. This study also found that doses above 4 mg once daily achieved drug exposures well above EC80 (the concentration that leads to an 80% maximal response) of the VEGFR phosphorylation inhibition over a 24-hour time period.

#### Studies in Colorectal Cancer

Phase Ib and II studies in third-line or above metastatic colorectal cancer patients in China

In December 2012, we initiated a Phase Ib study in patients with advanced colorectal cancer to compare the safety and tolerability of a 5 mg once daily 3-weeks-on/1-week-off regimen versus a 4 mg continuous once daily regimen. The study was divided into a randomized comparison study with 20 patients taking each regimen. The primary endpoint was the incidence of adverse effects, including significant adverse events, CTC grades 3 or 4 adverse effects and adverse effects that lead to dose interruption or dose discontinuation. In this study, both dose regimens demonstrated similar clinical efficacy and safety profile with the 5 mg once daily 3-weeks-on/1-week-off regimen showing slightly more favorable results. An additional 22 patients were subsequently enrolled into the 5 mg once daily 3-weeks-on/1-week-off regimen to further confirm the safety and tolerability of this regimen. As a result of this study, we determined the recommended Phase II dose regimen to be 5 mg, once daily, on a 3-weeks-on/1-week-off basis. Full results of this study were presented at the American Society of Clinical Oncology's annual meeting in 2014.

In August 2014, we completed enrollment for a Phase II, double-blind, placebo-controlled, multicenter study in China in just over four months to test fruquintinib as a monotherapy among third-line metastatic colorectal cancer patients, using the 5 mg daily, 3-weeks-on/1-week-off dose regimen determined from our Phase I study discussed above. The goal of this study was to compare the efficacy, including progression-free survival, of fruquintinib versus placebo in metastatic colorectal cancer patients who failed at least two prior lines of treatment, including fluorouracil, oxaliplatin and irinotecan. A total of 71 patients were enrolled, with 47 in the fruquintinib arm and 24 in the placebo arm, respectively. Patient baseline characteristics were similar between the two treatment arms.

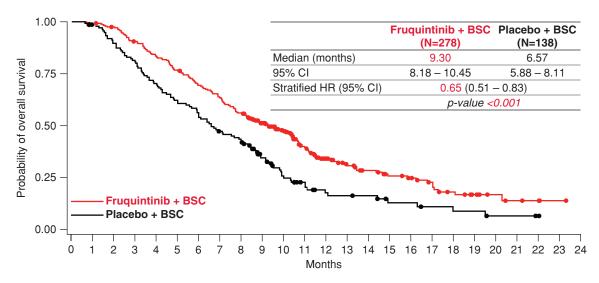
Fruquintinib demonstrated strong anti-tumor activity in this study. Median progression-free survival was 4.7 months in the fruquintinib arm compared to median progression-free survival of 1.0 month in the placebo arm (hazard ratio = 0.30 (p<0.001)). Hazard ratio is the probability of an event (such as disease progression or death) occurring in the treatment arm divided by the probability of the event occurring in the control arm of a study, with a ratio of less than one indicating a lower probability of an event occurring for patients in the treatment arm. P-value is a measure of the probability of obtaining the observed sample results, with a lower value indicating a higher degree of statistical confidence in these studies. The disease control rate in the fruquintinib arm was 68.1% compared with 20.8% in the placebo arm (p<0.001). The interim median overall survival rate was 7.6 months and 5.5 months in the fruquintinib arm and the placebo arm, respectively. In this study, fruquintinib has not shown any major unexpected safety issues and clearly met its primary endpoint of progression-free survival. The result of 4.7 months in median progression-free survival compares favorably with results recorded to date in third-line colorectal cancer in trials involving VEGFR tyrosine kinase inhibitors. The safety profile in this study was also consistent with our Phase Ib trial for fruquintinib in third-line metastatic colorectal cancer patients. The full results of this study were presented at the European Cancer Congress in September 2015.

Phase III study in colorectal cancer (third-line), fruquintinib monotherapy—China (Target Patient Population 15 in pipeline chart; Status: NDA submitted in June 2017; NCT02314819)

In December 2014, we initiated the FRESCO trial, which is a randomized, double-blind, placebo-controlled, multi-center, Phase III pivotal trial in patients with locally advanced or metastatic colorectal cancer who have failed at least two prior systemic antineoplastic therapies, including fluoropyrimidine, oxaliplatin and irinotecan. No drugs had been approved in third-line colorectal cancer in China with best supportive care being the general standard of care. Enrollment was completed in May 2016 and 519 patients were screened. The intent-to-treat population of 416 patients was randomized at a 2:1 ratio to receive either: 5 mg of fruquintinib orally once daily, on a three-weeks-on/one-week-off cycle, plus best supportive care (278 patients) or placebo plus best supportive care (138 patients). Randomization was stratified for prior anti-VEGF therapy and K-Ras gene status. The trial concluded in January 2017.

In June 2017, we highlighted the results of the FRESCO study in an oral presentation during the American Society of Clinical Oncology Annual Meeting held in Chicago. Results showed that FRESCO met all primary and secondary endpoints including significant improvements in overall survival and progression-free survival with a manageable safety profile and lower off-target toxicities compared to other targeted therapies. The primary endpoint of median overall survival was 9.30 months (95% confidence interval: 8.18-10.45) in the fruquintinib group versus 6.57 months (95% confidence interval: 5.88-8.11) in the placebo group, with a hazard ratio of 0.65 (95% confidence interval: 0.51-0.83; two-sided p<0.001). The secondary endpoint of median progression-free survival was 3.71 months (95% confidence interval: 3.65-4.63) in the fruquintinib group versus 1.84 months (95% confidence interval: 1.81-1.84) in the placebo group, with a hazard ratio of 0.26 (95% confidence interval: 0.21-0.34; two-sided p<0.001). Significant benefits were also seen in other secondary endpoints. The disease control rate in the fruquintinib group was 62.2% versus 12.3% for placebo (p<0.001), while the objective response rate based on confirmed responses was 4.7% versus 0% for placebo (p=0.012).

Figure 11: Phase III study in China of fruquintinib monotherapy in third-line colorectal cancer. FRESCO clearly succeeded in meeting the primary efficacy endpoint of OS.



In terms of safety, results showed that fruquintinib had a manageable safety profile with lower off-target toxicities compared to other VEGFR tyrosine kinase inhibitors. Of particular interest was that the CTC grade  $\geq 3$  hepatotoxicity was similar for the fruquintinib group as compared to the placebo group, which is in contrast to Stivarga which was markedly worse and often difficult to manage in this patient population in the CONCUR study. The most frequently reported fruquintinib-related CTC grade  $\geq 3$  adverse events included hypertension (21.2%), hand-foot skin reaction (10.8%), proteinuria (3.2%) and diarrhea (2.9%), all possibly associated with VEGFR inhibition. No other CTC grade  $\geq 3$  adverse events exceeded 1.4% in the fruquintinib population, including hepatic function adverse events such as elevations in bilirubin (1.4%), alanine aminotransferase (0.7%) or aspartate aminotransferase (0.4%). In terms of tolerability, dose interruptions or reductions occurred in only 35.3% and 24.1% of patients in the fruquintinib arm, respectively, and only 15.1% of patients discontinued treatment of fruquintinib due to adverse events versus 5.8% for placebo.

In June 2017, the CFDA acknowledged acceptance of the NDA for fruquintinib for the treatment of patients with advanced colorectal cancer. Fruquintinib was subsequently awarded priority review status in view of its clinical value, according to a CFDA announcement in September 2017.

#### Studies in Non-small Cell Lung Cancer

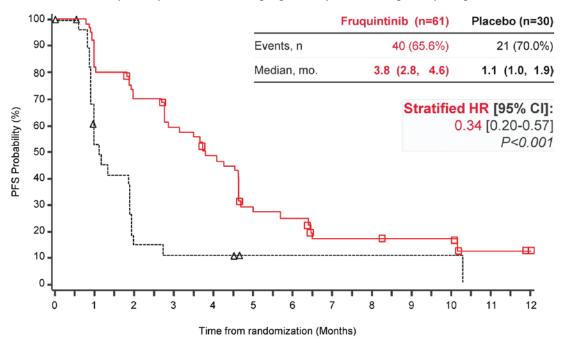
Phase II fruquintinib monotherapy in non-small cell lung cancer in China

In June 2014, we initiated a Phase II randomized, double-blind, placebo-controlled, multi-center study of fruquintinib versus placebo among patients with advanced non-squamous non-small cell lung cancer who failed two lines of chemotherapy. By early March 2015, enrollment had been completed with a total of 91 patients randomized to 5 mg of fruquintinib orally once per day, on a 3-weeks-on/1-week-off regimen plus best supportive care, or placebo plus best supportive care at a 2:1 ratio.

In September 2015, we reported that fruquintinib had clearly met its primary endpoint of superior median progression-free survival versus placebo in this study, and in December 2016, we reported the full data from this study at the 2016 World Conference on Lung Cancer, which showed median progression-free survival of 3.8 months for the fruquintinib group compared with 1.1 months for the placebo group (hazard ratio=0.34; 95% confidence interval: 0.20-0.57; p<0.001), an objective response rate based on confirmed partial responses of 13.1% for the fruquintinib group compared with 0.0% for the placebo group (p=0.041), and a 47.5% increase in disease control rate for the fruquintinib group compared with the placebo group (p<0.001). All were assessed by blinded independent clinical review. Fruquintinib was well tolerated with treatment related CTC grade  $\geq$ 3 adverse events with greater than 5% incidence being hypertension (8.1%).

Figure 12: Phase II study in China of fruquintinib monotherapy in third-line non-small cell lung cancer.

This study clearly met the median progression-free survival primary endpoint.



Source: Chi-Med

#### Studies in Gastric Cancer

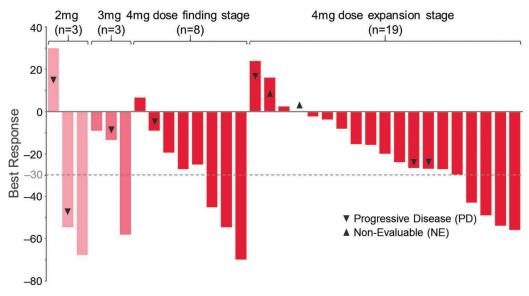
Phase Ib/II study of fruquintinib combined with Taxol in second-line gastric cancer patients in China

In early 2017, we completed an open label, multi-center Phase Ib dose finding/expansion study of fruquintinib in combination with Taxol in second-line gastric cancer. As of September 10, 2016, a total of 32 patients were enrolled in the study and the recommended dose was determined to be 4 mg once daily on

a 3-weeks-on/1-week-off schedule in combination with a weekly dose of 80 mg/m² of Taxol. A total of 28 out of the 32 patients were efficacy evaluable with an objective response rate of 36% (10/28, based on confirmed partial responses) and a disease control rate of 68% (19/28). At the recommended dose, progression-free survival of  $\geq$ 16 weeks was 50% of and overall survival of  $\geq$ 7 months was 50%. Tolerability of the recommended dose combination was as expected. In the drug expansion stage, CTC grade  $\geq$ 3 adverse events with greater than 5% incidence related to the treatment were neutropenia (57.9%), leukopenia (21.0%), hypertension (10.6%), decreased platelet count (5.3%), anemia (5.3%), hand-foot skin reaction (5.3%), mucositis oral (5.3%), hepatic disorder (5.3%), and upper gastrointestinal hemorrhage (5.3%), while neutropenia and leukopenia are common Taxol adverse events. The combination regime resulted in an approximately 30% increase in Taxol exposure in patients indicating the potential to decrease the required dose of Taxol in future development. In October 2017, based on the Phase Ib data, we initiated FRUTIGA, a pivotal Phase III clinical trial of fruquintinib in combination with Taxol in second-line gastric cancer. Updated results are expected to be published in an upcoming scientific journal.

Figure 13: Phase Ib/II study of fruquintinib combined with Taxol in gastric cancer. Phase III initiation made on the basis of these encouraging efficacy data.

## **Waterfall Plots of Best Response**



Source: Chi-Med

Note: As of November 30, 2016

# Fruquintinib Current Clinical Development and Near-Term Plans

As discussed below, we currently have various clinical trials of fruquintinib ongoing in China and the United States.

In partnership with Eli Lilly in China, we are conducting a Phase III study of fruquintinib in third-line non-small cell lung cancer patients, a Phase II study of fruquintinib in combination with Iressa in first-line non-small cell lung cancer patients, and a Phase III study of fruquintinib in combination with Taxol in second-line gastric cancer patients. In the United States, we have initiated Phase I study to evaluate the safety, tolerability and pharmacokinetics of fruquintinib in U.S. patients with advanced solid tumors.

#### Studies in Colorectal Cancer

Since completing submission of the NDA to the CFDA in early June 2017, we have engaged with the Center for Drug Evaluation to conduct reviews in the areas of (i) pharmacology and toxicity, (ii) clinical data and statistical analysis, and (iii) chemistry, manufacturing and control of standards and process. We have also facilitated the conduct of clinical site visits including GCP and good laboratory practice inspections. We are currently entering in the pre-approval inspection process for our active pharmaceutical ingredient contract manufacturer as well as the pre-approval inspection and GMP-certification process for our Suzhou formulation facility.

### Studies in Non-small Cell Lung Cancer

Phase III fruquintinib monotherapy in non-small cell lung cancer (third-line)—China (Target Patient Population 16 in pipeline chart; Status: enrollment complete; NCT02691299)

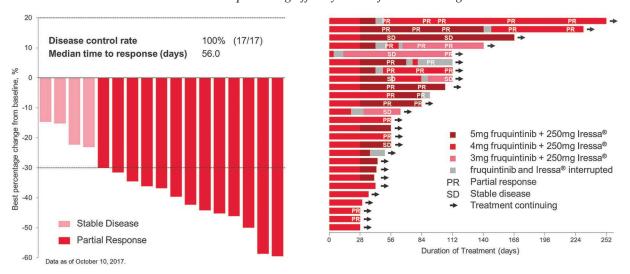
Following a positive Phase II study comparing fruquintinib with placebo in advanced non-squamous non-small cell lung cancer patients who have failed two prior systemic chemotherapies, or third-line non-small cell lung cancer, we initiated a Phase III registration study, the FALUCA study, in December 2015. In February 2018, we completed enrollment of the FALUCA study in China, in which a total of 527 patients were randomized at a 2:1 ratio to receive either 5 mg of fruquintinib orally once daily, on a 3-weeks-on/1-week-off cycle plus best supportive care, or placebo plus best supportive care. The primary endpoint for FALUCA is overall survival, with secondary endpoints including progression-free survival, objective response rate, disease control rate and duration of response. We expect to reach median overall survival endpoint maturity and report top-line results in late 2018.

Phase II study of fruquintinib in combination with Iressa in non-small cell lung cancer (first-line)—China (Target Patient Population 17 in pipeline chart; Status: enrolling; NCT02976116)

In early 2017, we initiated a multi-center, single-arm, open-label, dose-finding, Phase II study of fruquintinib in combination with Iressa in the first-line setting for patients with advanced or metastatic non-small cell lung cancer with EGFRm+. We have enrolled about 50 patients in this study with the objective to evaluate the safety and tolerability as well as efficacy of the combination therapy. Preliminary data were presented at the 2017 World Conference on Lung Cancer, with the 8 (31%) CTC grade  $\geq$ 3 treatment emergent adverse events being increased alanine aminotransferase (19%), increased aspartate aminotransferase (4%), proteinuria (4%) and hypertension (4%). There were no serious adverse events or those that lead to death. Preliminary results in 17 efficacy evaluable patients showed an objective response rate of 76% (13/17), including 9 confirmed and 4 unconfirmed partial responses at the time of data cut-off, as well as a disease control rate of 100% (17/17).

Fruquintinib's safety and tolerability profile, resulting from its high kinase selectivity, combined with flexibility to adjust dosage to manage treatment emergent toxicities due to its shorter half-life versus monoclonal antibody therapies, along with its potent anti-angiogenic effect, makes it a high potential combination partner for EGFR tyrosine kinase inhibitors. Subject to continued positive data in Target Patient Population 17, we will consider Phase III registration studies both inside and outside of China.

Figure 14: Phase II study of fruquintinib combined with Iressa in non-small cell lung cancer. Preliminary data showed promising efficacy in the first-line setting.



Phase I fruquintinib monotherapy in advanced solid tumors—United States (Target Patient Population 18 in pipeline chart; Status: enrolling; NCT03251378)

In December 2017, we initiated a multi-center, open-label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of fruquintinib in U.S. patients with advanced solid tumors. Upon completion, likely late in 2018, our intention is to begin exploring multiple innovative combination studies of fruquintinib and other tyrosine kinase inhibitors, chemotherapy and immunotherapy agents in the United States.

#### Studies in Gastric Cancer

Phase III study of fruquintinib in combination with Taxol in gastric cancer (second-line)—China (Target Patient Population 19 in pipeline chart; Status: enrolling)

In October 2017, we initiated the FRUTIGA study, a pivotal Phase III clinical trial of fruquintinib in combination with Taxol for the treatment in advanced gastric or gastroesophageal junction adenocarcinoma patients in China. This randomized, double-blind, placebo-controlled, multi-center trial is being conducted in patients with advanced gastric cancer who have progressed after first-line standard chemotherapy. Over 500 patients will be enrolled in the FRUTIGA study to evaluate the efficacy and safety of fruquintinib combined with paclitaxel compared with paclitaxel monotherapy for second-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma. The trial will enroll patients with disease that has been confirmed through histology or cytology and who did not respond to first-line standard chemotherapy containing platinum and fluorouracil. All subjects will receive fruquintinib or placebo combined with paclitaxel. Patients will be randomized at a 1:1 ratio and stratified according to factors such as stomach versus gastroesophageal junction tumors and ECOG performance status, a scale established by the Eastern Cooperative Oncology Group which determines ability of patient to tolerate therapies in serious illness, specifically for chemotherapy. An independent data monitoring committee will be established to review safety and efficacy data.

The primary efficacy endpoint is overall survival. Secondary efficacy endpoints include progression-free survival, objective response rate, disease control rate, duration of response and quality-of-life score (EORTC QLQ-C30, version 3.0). Biomarkers related to the antitumor activity of fruquintinib will also be explored. We intend to conduct an interim analysis of the FRUTIGA study for futility some time during 2019.

Advanced gastric cancer is a major medical need, particularly in Asian populations, with limited treatment options for patients who have failed first-line standard chemotherapy with 5-fluorouracil and platinum doublets. For gastric cancer, there are approximately 679,100 new cases and 498,000 deaths in China each year.

## Partnership with Eli Lilly

In October 2013, we entered into a license agreement with Eli Lilly in order to accelerate and broaden our fruquintinib development program in China. As a result, we were able to quickly expand the clinical development of fruquintinib in three indications with major unmet medical needs in China: colorectal cancer, non-small cell lung cancer and gastric cancer, as discussed above.

Contingent upon strong proof-of-concept and Phase III results in our clinical trials in China, Eli Lilly and Company (Eli Lilly's parent company) may exercise the option to help us develop fruquintinib globally under an option agreement into which we entered in connection with the license agreement. Support from Eli Lilly has also helped us to establish our manufacturing (formulation) facility in Suzhou, China, which now produces Phase III clinical supplies and will be used to produce fruquintinib for commercial supply, if approved.

For more information regarding our partnership with Eli Lilly and Eli Lilly and Company, see "—Overview of Our Collaborations."

## Sulfatinib VEGFR, FGFR1 and CSF-1R Inhibitor

As with fruquintinib, sulfatinib (also known as HMPL-012) was created as part of our initial research goals to develop better, more selective inhibitors than what was under late-stage development at the time, including inhibitors targeting VEGFR and FGFR, two tyrosine kinase receptors associated with angiogenesis and tumor growth. In early 2008, we declared our first small molecule oncology drug candidate, sulfatinib, and it was subsequently the first new compound IND application to be submitted, reviewed and approved by the CFDA under its "green channel" fast-track approval process.

Sulfatinib is an oral small molecule angio-immuno kinase inhibitor targeting VEGFR, FGFR1 and CSF-1R kinases that could simultaneously block tumor angiogenesis and immune evasion. Its unique angio-immuno kinase profile seems to support sulfatinib as an attractive candidate for exploration of possible combinations with checkpoint inhibitors against various cancers. Sulfatinib is currently in development as a single agent for neuroendocrine tumors, thyroid cancer and biliary tract cancer. It also has potential in other tumor types such as breast cancer with FGFR1 activation.

Our expanded Phase I data indicated that sulfatinib has the highest objective response rate reported to date in patients with neuroendocrine tumors. An objective response rate of 38.1% in the intent-to-treat population was observed for sulfatinib in this study, compared to less than 10.0% for Sutent and Afinitor, the two approved single agent therapies for neuroendocrine tumors.

Sulfatinib is the first oncology candidate that we have taken through proof-of-concept in China and expanded globally ourselves. We believe sulfatinib has the potential to receive Breakthrough Therapy designation for the treatment of neuroendocrine tumors if in the U.S. Phase II study we are able to achieve an objective response rate in line with that seen to date. A U.S. Phase I study is close to completion and we are planning a proof-of-concept study in neuroendocrine tumors in the United States.

## **Mechanism of Action**

Both VEGFR and FGFR signaling pathways can mediate tumor angiogenesis. CSF-1R plays an important role on functions of macrophages. Recently, the roles in increasing tumor immune evasion of VEGFR, FGFR in regulation of T cells, tumor-associated macrophages and myeloid-derived suppressor cells have been demonstrated. Therefore, blockade of tumor angiogenesis and tumor immune evasion by

simultaneously targeting VEGFR, FGFR and CSF-1R kinases may represent a promising approach for anti-cancer therapy.

For more information on the VEGF mechanism of action, see "—Our Clinical Pipeline—Fruquintinib VEGFR 1, 2 and 3 Inhibitor—Mechanism of Action."

#### Sulfatinib Pre-clinical Evidence

Sulfatinib inhibited VEGFR1, 2, and 3, FGFR1 and CSF-1R kinases with  $IC_{50}$  in a range of 1 nM to 24 nM. It also strongly blocked VEGF-induced VEGFR2 phosphorylation in HEK293KDR cells and CSF-1R phosphorylation in RAW264.7 cells with an  $IC_{50}$  of 2 nM and 79 nM, respectively. Sulfatinib also reduced VEGF- or FGF-stimulated human umbilical vein endothelial cell proliferation with an  $IC_{50} < 50$  nM. In animal studies, a single oral dose of sulfatinib inhibited VEGF-stimulated VEGFR2 phosphorylation in lung tissues of nude mice in an exposure-dependent manner. Furthermore, elevation of FGF23 levels in plasma 24 hours post dosing suggested suppression of FGFR signaling.

Sulfatinib demonstrated potent tumor growth inhibition in multiple human xenograft models and decreased cluster of differentiation 31 expression remarkably, suggesting strong inhibition on angiogenesis through VEGFR and FGFR signaling. In a syngeneic murine colon cancer model, sulfatinib demonstrated moderate tumor growth inhibition after single-agent treatment. Flow cytometry and immunohistochemistry analysis revealed an increase of certain T cells and a significant reduction in certain tumor-associated macrophages, including CSF-1R mutation positive tumor-associated macrophages in tumor tissue, indicating sulfatinib has a strong effect on CSF-1R. Interestingly, a combination of sulfatinib with a programmed death-ligand 1 antibody resulted in enhanced anti-tumor effect. These results suggested that sulfatinib has a strong effect in modulating angiogenesis and cancer immunity.

## Sulfatinib Early and Completed Clinical Development

As discussed below, we have completed two clinical trials of sulfatinib in China.

First-in-human Phase Ia trial

The multi-center, open-label, dose escalation, first-in-human Phase I study of sulfatinib was initiated in China in April 2010. Its primary objective was to study the safety and tolerability and determine the maximum tolerated dose or the recommended Phase II dose of sulfatinib in patients with advanced malignant solid tumors. Secondary endpoints included pharmacokinetic properties and clinical efficacy. The study consisted of a dose escalation period and dose expansion period. The initial sulfatinib dose was 50 mg, once daily. By April 2014, 12 dose groups of 50-350 mg sulfatinib per day had completed the dose escalation study. The maximum tolerated dose was not reached. However, the drug exposures appeared to stop increasing in proportion to dose from 300 mg to 350 mg. In addition, encouraging activity was seen both at 300 and 350 mg doses. A dose expansion study was conducted at the 300 mg and 350 mg dose levels to further investigate the safety, tolerability and pharmacokinetic profile, and preliminary efficacy of sulfatinib. Final results as of July 2015 were published in Oncotarget in February 2017.

A total of 77 patients were enrolled in the study. The first 43 patients were enrolled in sulfatinib, formulation 1, in 50 mg, 75 mg, 110 mg, 150 mg, 200 mg, 265 mg and 300 mg once daily, as well as 125 mg and 150 mg twice daily dose cohorts. As the study progressed, a new milled formulation, formulation 2, was developed with an improved pharmacokinetic profile to replace formulation 1 and was used in the remaining study. There was no subject treated with sulfatinib cross-over by formulations (i.e., no subject receiving formulation 1 had crossed over to formulation 2 during study treatment). A total of 34 patients were enrolled and treated with sulfatinib formulation 2. 23 of the patients were enrolled in the formulation 2 dose escalation study in dose cohorts of 200 mg, 300 mg and 350 mg once daily, and a further 11 were enrolled in an expansion study in dose cohorts of 300 mg and 350 mg once daily. All 34 patients on

formulation 2 completed the safety and pharmacokinetic evaluation. The maximum tolerated dose was also not reached in this formulation.

CTC grade  $\geq 3$  adverse events observed in formulation 2 patients with greater than 5% incidence include proteinuria (14.7%), hypertension (8.8%), increased aspartate aminotransferase (5.9%), diarrhea (5.9%), decreased hemoglobin (5.9%), decreased platelet count (5.9%) and hypophosphatemia (5.9%). No dose-limiting toxicity was observed, and maximum tolerated dose has not been determined. Overall, in this Phase I dose escalation study, sulfatinib showed a safety profile that is comparable to the other drugs in the same class and that, as a single agent, it was well tolerated in patients with advanced solid tumors.

Pharmacokinetic analyses showed that the inter- and intra-individual variability in drug concentration was optimized and the exposures in terms of Cmax, or the maximum concentration that a drug achieves in a specified test area of the body after the drug has been administrated and prior to the administration of a second dose, and AUC were increased compared with formulation 2, indicating optimized oral absorption. Phase Ia pharmacokinetic profile of sulfatinib in humans was consistent with pre-clinical findings in that sulfatinib at the 300 mg Phase II dose provides for consistent and sustained target inhibition over 24 hours through an oral dose.

In terms of Phase Ia efficacy, among 34 patients treated with formulation 2, 28 patients were evaluable by Response Evaluation Criteria in Solid Tumors Version 1.0 criteria, of which nine achieved confirmed partial response, including one patient with hepatocellular carcinoma receiving sulfatinib 200 mg once daily, and eight with neuroendocrine tumors receiving sulfatinib 300 or 350 mg once daily. There were 15 patients with stable disease (10 with neuroendocrine tumors, three with hepatocellular carcinoma, one with gastrointestinal stromal tumors, and one with an abdominal malignancy) and four patients with progressive disease. Based on confirmed responses, the objective response rate amongst all patients treated with sulfatinib formulation 2 was 26.5% (9/34) and the disease control rate was 70.6% (24/34), or an objective response rate of 32.1% (9/28) and a disease control rate was 85.7% (24/28) amongst efficacy evaluable formulation 2 patients. The recommended Phase II dose was determined to be 300 mg once daily based on overall safety, tolerability and early clinical efficacy results.

Favorable clinical efficacy has been seen with sulfatinib in patients with neuroendocrine tumors. The formulation 2 expansion study was conducted in neuroendocrine tumor patients who were given 300 mg or 350 mg once daily. Including dose escalation patients, a total of 21 neuroendocrine tumor patients were treated with formulation 2. There were eight confirmed partial response patients, 10 stable disease patients, and three patients were not evaluable for response. This yielded an objective response rate of 44.4% in the 18 evaluable neuroendocrine tumor patients and 38.1% in the entire intent-to-treat population of 21 neuroendocrine tumor formulation 2 patients (compared to an objective response rate of less than 10% for competing products, Sutent and Afinitor). The tumor origins of the eight neuroendocrine tumor patients with partial responses include pancreas (three patients), duodenum (one patient), rectum (one patient) and thymus (one patient), with the remaining two patients' tumors of unknown origin. Furthermore, neuroendocrine tumor responses to sulfatinib have been observed to improve gradually with time.

This early preliminary clinical efficacy of sulfatinib compares favorably to existing drugs approved for the treatment of neuroendocrine tumors. As shown below, however, approved therapies for neuroendocrine tumors are very limited with Afinitor and Sutent approved only for pancreatic neuroendocrine tumors (representing less than 10% of total neuroendocrine tumors) and showing an objective response rate of less than 10% compared to 38% for sulfatinib. The somatostatin analogues octreotide and lanreotide are also approved for narrow subsets of gastrointestinal neuroendocrine tumors, but their objective response rate is less than 5%. In January 2018, the FDA approved Lutathera (lutetium Lu 177 dotatate) injection, a radiolabeled somatostatin analog which, like octreotide and lanreotide, is indicated for the treatment of somatostatin receptor-positive neuroendocrine tumors (gastroenteropancreatic in the case of Lutathera), and has a half-life of less than seven days. Sulfatinib's

superior objective response rate, and apparent efficacy across many different neuroendocrine tumor types, as compared to existing approved therapies, are the basis for our view that sulfatinib could potentially be eligible for Breakthrough Therapy designation.

Phase Ib/II study in neuroendocrine tumors (first-line), sulfatinib monotherapy (300 mg) in China

In early 2015, we began a 30-patient, 300 mg daily, Phase Ib study in China in broad spectrum neuroendocrine tumor patients (pancreatic, gastrointestinal, liver, lymph and lung, among others) which, due to the major unmet medical need and strong efficacy of sulfatinib, was expanded to over 65 patients and enrollment was completed in August 2015. We then amended the protocol from a Phase Ib study to a single arm Phase II study for which enrollment of 81 patients (41 with pancreatic neuroendocrine tumors and 40 with extra-pancreatic neuroendocrine tumors) was completed in December 2015.

The majority of the patients enrolled in this Phase II study had grade 2 diseases (79%) and had failed previous systemic treatments (65%). We reported the results of this Phase II study at the 2017 European Neuroendocrine Tumor Society conference. As of January 2017, 13 patients had confirmed partial response and 61 patients had stable disease corresponding to an overall objective response rate of 16.0%, with 17.1% in pancreatic neuroendocrine tumors and 15.0% in extra-pancreatic neuroendocrine tumors, and an overall disease control rate of 91.4%. Median overall progression-free survival has not been reached, but is estimated to be 16.6 months, with as-expected, longer median progression-free survival in pancreatic neuroendocrine tumors estimated to be 19.4 months and shorter median progression-free survival in extra-pancreatic neuroendocrine tumors estimated to be 13.4 months. Importantly, in the context of our potential global development strategy, there were 14 patients who had progressed after treatment with systemic therapies (Sutent and Afinitor) and all benefited from the sulfatinib treatment (four patients with partial response and 10 patients with stable disease). Sulfatinib was well tolerated with adverse events CTC grade ≥3 with greater than 5% incidence being hypertension (30.9%), proteinuria (13.6%), hyperuricemia (9.9%), hypertriglyceridemia (8.6%), diarrhea (7.4%) and alanine aminotransferase increase (6.2%). Based on this promising efficacy data and tolerability in patients with advanced pancreatic neuroendocrine tumors, two randomized Phase III trials, SANET-p and SANET-ep, have been initiated, as discussed below.

A. Pancreatic NET Waterfall Chart. C. Progression-Free Survival (PFS) Median PDs or PFS Deaths 10% (months (% pts) 80% 0% All NET 16.6m 51.9% -10% (13.4, 19.4)(42/81)60% -20% 19.4m 39.0% P-NET -30% (n=41)(13.8, 22.1) (16/41)-40% All NET 20% Non-P Pancreatic NET 13.4m -50% ITT Evaluable NET Non-pancreatic NET (7.6, 16.7)(26/40)-60% (n=40)ORR: 17.1% (7/41)18.4% (7/38)-70% 9 12 15 Data has yet to reach maturity - data cut-off as of Jan 20, 2017. DCR: 90.2% (37/41) 97.4% (37/38) Partial Response Stable Disease Progressive disease Prior Sutent® Prior Famitinib (VEGFR) ■ Prior Afinitor® ▲ Progressive Disease on Prior TKI B. Non-Pancreatic NET Waterfall Chart. D. Adverse Events rade ≥3 (≥4pts n (%) n (%) 10% Hypertension 25 (30.9) 81 (100.0) Any AE Proteinuria 11 (13.6) Grade ≥3 AE 63 (77.8) -10% Any SAE 8 (9.9) 21 (25.9) Hyperuricemia -20% Hypertriglyceridemia 7 (8.6) Any drug-related AE 81 (100) Diarrhea 6 (7.4) Any drug-related grade ≥3 AE 58 (71.6) -40% ALT increased 5 (6.2) Any drug related SAE 10 (12.3) Drug related AE leading -50% Anemia 4 (4.9) ITT Evaluable Hypokalemia 4 (4.9) 40 (49.4) -60% ORR: 15.0% (6/40)15.8% (6/38)dose reduction 20 (24.7) Hepatic function -70% 4 (4.9) DCR: 92.5% (37/40) 97.4% (37/38) drug withdrawal 7 (8.6)

Figure 15: Phase II study in China of sulfatinib monotherapy in neuroendocrine tumors.

Interim data demonstrates promising efficacy.

Source: European Neuroendocrine Tumour Society Annual Conference 2017. Data cut-off as of January 20, 2017.

### Sulfatinib Current Clinical Development and Near-Term Plans

We currently have various clinical trials of sulfatinib ongoing or expected to begin in the near term in China and the United States. Based on the data from our completed Phase Ib/II study in China in neuroendocrine tumors discussed above, we are progressing to two Phase III trials in China, one in pancreatic neuroendocrine tumor patients and one in advanced carcinoid (extra-pancreatic neuroendocrine) tumors, with the extra-pancreatic neuroendocrine tumor study having started enrollment in December 2015 and the pancreatic neuroendocrine tumor study having started enrollment in March 2016. A Phase I dose escalation study in Caucasian patients in the United States is close to completion. Additionally, two Phase II studies of sulfatinib as monotherapy are ongoing in China for recurrent/refractory thyroid cancer patients, with another Phase II study being conducted with Gemzar (gemcitabine) refractory biliary tract cancer patients.

### Studies in Neuroendocrine Tumors

Phase III study in pancreatic neuroendocrine tumors, sulfatinib monotherapy—China (Target Patient Population 20 in pipeline chart; Status: enrolling; NCT02589821)

In March 2016, we initiated the SANET-p study, which is a Phase III study in patients with low- or intermediate-grade, advanced pancreatic neuroendocrine tumors. In this study, patients are randomized at a two-to-one ratio to receive either an oral dose of 300 mg of sulfatinib once daily or placebo on a 28-day treatment cycle. The primary endpoint is progression-free survival, with secondary endpoints an oral dose of including objective response rate, disease control rate, time to response, duration of response, overall survival, safety and tolerability. We expect to complete enrollment in 2019 and present top-line results thereafter. If the SANET-p Phase III data is consistent with the 17.1% objective response rate and

estimated 19.4 month median progression-free survival reported in the above-mentioned Phase Ib/II study, we believe the benefits of sulfatinib as a monotherapy to the approximately 5,000 to 6,000 new patients with pancreatic neuroendocrine tumors in China will be significant as compared to the treatment alternatives currently available to them.

Phase III study in extra-pancreatic neuroendocrine tumors, sulfatinib monotherapy—China (Target Patient Population 21 in pipeline chart; Status: enrolling; NCT02588170)

In December 2015, we initiated the SANET-ep study, which is a Phase III study in patients with low-or intermediate-grade advanced extra-pancreatic neuroendocrine tumors. In this study, patients are randomized at a 2:1 ratio to receive either 300 mg of sulfatinib orally daily or placebo, on a 28-day treatment cycle. The primary endpoint is progression-free survival, with secondary endpoints including objective response rate, disease control rate, time to response, duration of response, overall survival, safety and tolerability. We expect to complete enrollment in 2019 and present top-line results thereafter. If the SANET-ep Phase III data is consistent with the 15.0% objective response rate and estimated 13.4 month median progression-free survival reported in the above-mentioned Phase II study, we believe the benefit of sulfatinib as a monotherapy to patients with extrapancreatic neuroendocrine tumors in China will be significant as compared to the minimal treatment alternatives currently available to them.

Phase I sulfatinib monotherapy in advanced solid tumors—United States (Target Patient Population 22 in pipeline chart; Status: enrolling; NCT02549937)

A Phase I study in cancer patients in the United States is now close to completion, having confirmed the Recommended Phase 2 dose.

We are currently in final planning for an expansion of sulfatinib development in the United States into a multi-arm Phase IIa study to explore efficacy and safety in both neuroendocrine tumor patients and solid tumor cancer patients.

Phase II sulfatinib monotherapy in recurrent/refractory thyroid cancer—China (Target Patient Populations 23 and 24 in pipeline chart; Status: enrollment complete; NCT02614495)

In March 2016, we initiated two Phase II studies in China to evaluate the safety, pharmacokinetics and efficacy of sulfatinib in patients with both medullary and differentiated thyroid cancer and are observing encouraging early efficacy in these open-label studies. We believe that sulfatinib's VEGFR/FGFR1/CSF-1R inhibition profile has strong potential in second-line thyroid cancer patients, particularly in China where there are few safe and effective treatment options for this patient population.

In June 2017, we presented preliminary results of the Phase II studies at the 2017 American Society of Clinical Oncology Annual Meeting and at the American Thyroid Association Annual Meetings. The preliminary data in 16 efficacy evaluable patients showed an objective response rate based on confirmed responses of 30% (3/10) in differentiated thyroid cancer and an objective response rate of 16.7% (1/6) in medullary thyroid cancer, with all other patients reporting stable disease.

Phase II sulfatinib monotherapy in chemotherapy refractory biliary tract cancer—China (Target Patient Population 25 in pipeline chart; Status: enrolling NCT02966821)

In January 2017, we began a Phase II study in patients with biliary tract cancer (also known as cholangiocarcinoma), a heterogeneous group of rare malignancies arising from the biliary tract epithelia. Gemzar is the currently approved first-line therapy for biliary tract cancer patients, with a total of approximately 18,000 new patients per year in the United States according to the National Cancer Institute, but median survival is less than 12 months for patients with unresectable or metastatic disease at diagnosis. As a result, we see a major unmet medical need for patients who have progressed on Gemzar, and sulfatinib may offer a new targeted treatment option in this tumor type.

### Epitinib EGFR Inhibitor

Epitinib (also known as HMPL-813) is a potent and highly selective oral EGFR inhibitor designed to optimize brain penetration. A significant portion of patients with non-small cell lung cancer go on to develop brain metastasis. Patients with brain metastasis suffer from poor prognosis and low quality of life with limited treatment options. Epitinib is a potent and highly selective oral EGFR inhibitor which has demonstrated brain penetration and efficacy in pre-clinical and now clinical studies. EGFR inhibitors have revolutionized the treatment of non-small cell lung cancer with EGFR activating mutations. However, approved EGFR inhibitors such as Iressa and Tarceva cannot penetrate the blood-brain barrier effectively, leaving the majority of patients with brain metastasis without an effective targeted therapy.

Our strategy has been to create targeted therapies in the EGFR area that would go beyond the already approved EGFRm+ non-small cell lung cancer patient population to address certain areas of unmet medical needs that represent significant market opportunities, including: (i) brain metastasis and/or primary brain tumors with EGFRm+, which we seek to address with epitinib; and (ii) tumors with EGFR gene amplification or EGFR over-expression, which we seek to address with theliatinib as discussed below.

#### **Mechanism of Action**

EGFR is a protein that is a cell-surface receptor tyrosine kinase for epidermal growth factor. Activation of EGFR can lead to a series of downstream signaling activities that activate tumor cell growth, survival, invasion, metastasis and inhibition of apoptosis. Tumor cell division can happen uncontrollably when the pathway is abnormally activated through EGFRm+, gene amplification of wild-type EGFR or over-expression of wild-type EGFR. Treatment strategies for certain cancers involve inhibiting EGFRs with small molecule tyrosine kinase inhibitors. Once the tyrosine kinase is disabled, it cannot activate the EGFR pathway and trigger downstream signaling activities, thereby suppressing cancer cell growth.

Outside of non-small cell lung cancer, EGFRm+ also occurs in glioblastoma, a common type of malignant primary brain tumor.

### **Epitinib Pre-clinical Evidence**

Pre-clinical studies and orthotopic brain tumor models have shown that epitinib demonstrated brain penetration and efficacy superior to that of current globally marketed EGFRm+ inhibitors such as Iressa and Tarceva. In orthotopic brain tumor models, epitinib demonstrated good brain penetration, efficacy and pharmacokinetic properties as well as a favorable safety profile.

If the pre-clinical findings on drug exposure of epitinib in the brain are confirmed in humans in our clinical trials, we believe epitinib has the potential to qualify for U.S. Breakthrough Therapy designation for patients with EGFRm+ non-small cell lung cancer with tumors metastasized to the brain.

#### **Epitinib Early Clinical Development**

As discussed below, we have completed two clinical trials of epitinib in China.

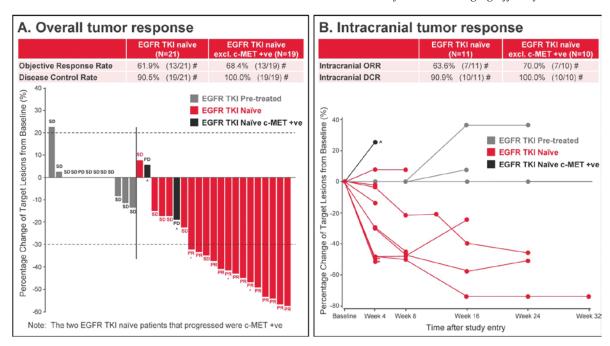
Phase I epitinib monotherapy in non-small cell lung cancer—China

This first-in-human study was conducted to assess the maximum tolerated dose and dose-limiting toxicity, safety and tolerability, pharmacokinetics, and preliminary anti-tumor activity of epitinib. As of December 2014, 36 patients were enrolled in seven cohorts (20 mg, 40 mg, 80 mg, 120 mg, 160 mg, 200 mg and 240 mg). This study found that the safety and tolerability of epitinib was acceptable. No dose-limiting toxicity was observed, and the maximum tolerated dose was not reached. The recommended dose from this study was 160 mg once daily based on pharmacokinetics data and safety data.

Phase Ib epitinib monotherapy in non-small cell lung cancer (first-line), EGFRm+ with brain metastasis, (160 mg daily)—China

In this Phase Ib study, a total of 33 non-small cell lung cancer patients, of which 12 had previously received EGFR tyrosine kinase inhibitor treatment and 21 were EGFR tyrosine kinase inhibitor treatment naïve, were efficacy evaluable with an objective response rate of 39%, including 10 confirmed and three unconfirmed partial responses. All responses occurred in EGFR tyrosine kinase inhibitor treatment naïve patients resulting in an objective response rate of 62% and in the 11 EGFR tyrosine kinase inhibitor naïve patients who also had measurable brain metastasis (lesion diameter>10 mm per Response Evaluation Criteria In Solid Tumors 1.1) with a 64% objective response rate. Furthermore, when patients with c-Met gene amplification were excluded, epitinib's objective response rate increased to 68% in the EGFR tyrosine kinase inhibitor treatment naïve patients and 70% of those patients who also had measurable brain metastasis. Epitinib was well tolerated with treatment related adverse events in the dose expansion stage CTC grade  $\geq$ 3 with greater than 10% incidence were elevations in alanine transaminase (18.9%), elevations in gamma-glutamyltransferase (10.8%), and aspartate transaminase (10.8%).

Figure 16: Phase Ib study in China of epitinib monotherapy in EGFRm+ non-small lung cancer patients with brain metastasis. Phase III initiation made on the basis of this encouraging efficacy data



Dose expansion stage—data cut-off Sept 20, 2016; \* Unconfirmed partial response, due to no further assessment at cut-off date; # Includes both confirmed and unconfirmed partial response; ^ c-MET amplification/high expression identified

Source: Chi-Med

#### **Epitinib Current Clinical Development and Near-Term Plans**

As discussed below, are currently planning to initiate two clinical studies of epitinib in China, including one Phase III trial.

Phase Ib epitinib monotherapy in non-small cell lung cancer, EGFRm+ with brain metastasis—China (Target Patient Population 26 in pipeline chart; Status: continues to enroll; NCT02590952)

In December 2016 at the World Conference on Lung Cancer, we presented encouraging efficacy data for an open label, multi-center, Phase I dose expansion study. Patients treated with epitinib at a 160 mg once daily dose (detailed above). During 2017, we continued to enroll patients in this Phase Ib study exploring a lower 120 mg once daily dose in the context of further optimizing tolerability for long-term usage. We expect to decide the Phase III dose in early 2018 and initiate Phase III shortly thereafter.

Phase Ib/II epitinib monotherapy in glioblastoma—China (Target Patient Population 27 in pipeline chart; Status: enrolling; NCT03231501)

Glioblastoma is the most aggressive of the gliomas, which are tumors that arise from glial cells or their precursors within the central nervous system. Glioblastoma is classified as grade IV under the World Health Organization grading of central nervous system tumors, and is the most common brain and central nervous system malignancy, accounting for 46.6% of such tumors. In 2017, there were approximately 12,000 new glioblastoma cases in the United States, according to the Central Brain Tumor Registry of the United States. In 2015, there were approximately 101,600 new brain or central nervous system cancer cases in China. The standard of care for treatment is surgery, followed by radiotherapy and chemotherapy. Median survival is approximately 15 months, and the 5-year survival rate is 5.5%. There are limited treatment options for glioblastoma patients, particularly for patients with recurrent glioblastoma.

Epitinib is a highly differentiated EGFR inhibitor designed for optimal blood-brain barrier penetration. EGFR gene amplification has been identified in about half of glioblastoma patients, according to The Cancer Genome Atlas Research Network, and hence is a potential therapeutic target in glioblastoma.

In March 2018, we initiated a Phase Ib/II proof-of-concept study of epitinib in glioblastoma patients with EGFR gene amplification in China. This Phase Ib/II study will be a multi-center, single-arm, open-label study to evaluate the efficacy and safety of epitinib as a monotherapy in patients with EGFR gene amplified, histologically confirmed glioblastoma. The primary endpoint is objective response rate.

### Theliatinib EGFR Inhibitor

Like epitinib, theliatinib (also known as HMPL-309) is a novel molecule EGFR inhibitor being investigated for the treatment of esophageal and other solid tumors. Tumors with wild-type EGFR activation, for instance, through gene amplification or protein over-expression, are less sensitive to EGFR tyrosine kinase inhibitors such as Iressa and Tarceva due to sub-optimal binding affinity. Theliatinib was designed with strong affinity to the wild-type EGFR kinase and has demonstrated five to ten times the potency than Tarceva in pre-clinical trials. This holds importance because tumors with wild-type EGFR activation have been found to be less sensitive to current EGFR inhibitors. This is notable in certain cancer types such as esophageal cancer, where 8-30% have EGFR gene amplification and 30-90% have EGFR over-expression. As a result, we believe that theliatinib could potentially be more effective than existing EGFR tyrosine kinase inhibitor products and benefit patients with esophageal and head and neck cancer, or other tumor types with a high incidence of wild-type EGFR activation. We currently retain all rights to theliatinib worldwide.

#### Mechanism of Action

Unlike c-Met, where targeted therapies have yet to be approved in the patient population with c-Met over-expression, there are successful examples of clinical efficacy among patients with EGFR over-expression in tumor types such as colorectal cancer and head and neck cancer. The most successful targeted therapy in the patient population with EGFR over-expression is the monoclonal antibody, Erbitux (cetuximab) (from Bristol Myers Squibb/Merck Serono), which is indicated for head and neck cancer and

colorectal cancer. Importantly, there remain many tumor types with high levels of EGFR over-expression for which no targeted therapies have been approved. In addition, in patients with EGFR gene amplification, there are no approved targeted therapies despite high levels of EGFR gene amplification occurring in many of the above EGFR over-expressed tumor types.

#### Theliatinib Pre-clinical Evidence

EGFR is over-expressed in a significant proportion of epithelium-derived carcinomas, which are cancers that begin in a tissue that lines the inner or outer surfaces of the body. Theliatinib inhibits the epidermal growth factor-dependent proliferation of cells at nanomolar concentrations. Of most interest is the strong binding affinity to wild-type EGFR enzyme demonstrated by theliatinib. The data indicated that upon withdrawal of the drug, the EGFR phosphorylation rapidly returns to higher levels for Iressa and Tarceva, while EGFR phosphorylation remained low for theliatinib after drug withdrawal, suggesting theliatinib may demonstrate a sustained target occupancy or "slow-off" characteristic due to strong binding, as shown in Figure 17 below.

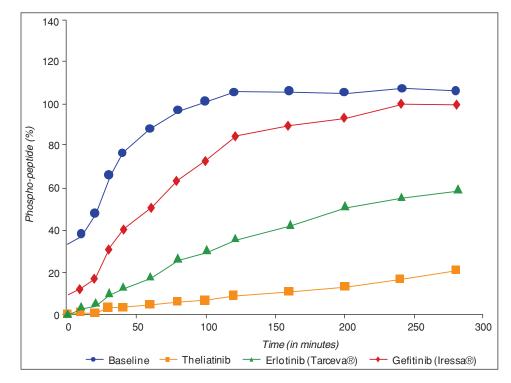


Figure 17: Comparison of binding affinity to wild-type EGFR enzyme

Source: Chi-Med

Note: When adenosine triphosphate (ATP) binds to an EGFR enzyme, the enzyme phosphorylates its peptide substrate to produce phosphorylated peptide, or phospho-peptide. Hence, low phospho-peptide levels are correlated with a high level of EGFR inhibition.

#### Theliatinib Current Clinical Development and Near-Term Plans

As discussed below, we currently have two clinical trials of theliatinib ongoing in China.

Phase I study of theliatinib monotherapy in advanced solid tumors—China (Target Patient Population 28 in pipeline chart; Status: enrollment complete; NCT02601274)

In November 2012, we initiated the first-in-human Phase I, open-label, dose escalation study in China of theliatinib administered orally to patients with wild-type EGFR gene amplification or EGFR over-expression solid tumors who have failed standard therapy. The primary objectives of the study were to evaluate its safety and tolerability in patients with advanced solid tumors and to determine the maximum tolerated dose. The study also evaluated efficacy against non-small cell lung cancer, esophageal cancer and head and neck squamous cell lung cancer, determined the pharmacokinetics of theliatinib under single dose and repeat doses; and explored the relationship between the theliatinib's activity and certain biomarkers.

In September 2017, new clinical data were presented at the  $20^{th}$  Annual Meeting of the Chinese Society of Clinical Oncology. Results showed that doses up to 500 mg once daily were determined to be safe and well-tolerated, with no dose-limiting toxicities and no clear maximum tolerated dose. Pharmacokinetic exposure increased with dose, with a 300 mg once daily or more considered to be sufficient to inhibit EGFR phosphorylation. Among the 21 patients that received 120 mg to 500 mg once daily, there were only four treatment-emergent adverse events of grade  $\geq$ 3: gastrointestinal bleeding, decreased white blood cell count, anemia or decreased platelet count (1/21 = 4.8% each). There were no incidences of grade  $\geq$ 3 rash or diarrhea. Among seven esophageal cancer patients, five had measurable lesions and could be evaluated for response. All five had stable disease. Of the efficacy evaluable patients in the 120 mg to 500 mg cohorts, 44.4% (8/18) had stable disease after 12 weeks. The study concluded that further study of theliatinib at 400 mg once daily among esophageal cancer patients with EGFR activation was warranted. This study is now in the process of expanding through the opening of further clinical sites in China.

Phase Ib expansion study of theliatinib monotherapy in esophageal cancer—China (Target Patient Population 29 in pipeline chart; Status: enrolling; NCT02601274)

In January 2017, we initiated a Phase Ib proof-of-concept expansion study at 300 mg of theliatinib once daily in esophageal cancer patients with EGFR protein overexpression or gene amplification.

## HMPL-523 Syk Inhibitor

The result of our over six-year program of discovery and pre-clinical work against Syk is HMPL-523, a highly selective Syk inhibitor with a unique pharmacokinetic profile which provides for higher drug exposure in the tissue than on a whole blood level. We designed HMPL-523 intentionally to have high tissue distribution because it is in the tissue that the B-cell activation associated with rheumatoid arthritis and lupus occurs most often. Furthermore, and somewhat counter intuitively, in hematological cancer the vast majority of cancer cells nest in tissue, with a small proportion of cancer cells releasing and circulating in the blood where they cannot survive for long. In both rheumatoid arthritis and hematological cancer, we assessed that an effective small molecule Syk inhibitor would need to have superior tissue distribution.

However, many pharmaceutical and biotechnology companies had experienced difficulties in developing a safe and efficacious Syk-targeted drug. For example, the development of the Syk inhibitor fostamatinib for rheumatoid arthritis was one such failed program, although clear efficacy was observed in Phase II and Phase III trials. The main problem was off-target toxicities associated with poor kinase selectivity, such as hypertension and severe diarrhea. Therefore, we believe that kinase selectivity is critical to a successful Syk inhibitor. In addition, fostamatinib was designed as a prodrug in order to improve solubility and oral absorption. A prodrug is medication administered in a pharmacologically inactive form which is converted to an active form once absorbed into circulation. The rate of the metabolism required to release the active form can vary from patient to patient, resulting in large variation in active drug exposures that can impact efficacy. We believe HMPL-523 offers important advantages over intravenous

monoclonal antibody immune modulators in rheumatoid arthritis in that small molecule compounds clear the system faster, thereby reducing the risk of infections from sustained suppression of the immune system.

#### Mechanism of Action

Targeting the B-cell signaling pathway is emerging as a potential means to treat both hematological cancer and immunology. Both PI3K $\delta$  and BTK (both kinases) along the B-cell signaling pathway have proven clinical efficacy in hematological cancers, and consequently the FDA has approved drugs targeting these kinases in the past few years. Syk is a key kinase upstream of the PI3K $\delta$  and BTK, and we believe should therefore be an important target for modulating B-cell signaling.

Antigen **Antigen** Extracellular Intracellular Lyn CD79 a HMPL-523 CD79 B GS-9876 entospletinib ΡΙ3Κδ PLCy-2 втк idelalisib HMPL-689 ibrutinib PKC **mTOR** Cell activation, proliferation, survival, and migration

Figure 18: The B-cell signaling pathway and the approved drugs / drug candidates which target its component kinases

Source: Chi-Med

Note: This graphic is a highly simplified representation of the B-cell signaling pathways, which are each composed of a signaling cascade of the multiple kinases indicated in the graphic. Signaling from the B-cell receptor (BCR) through the cascade, in simple terms, triggers an immune response, including tumor cell activation, proliferation, survival and migration.

### Syk, a target for autoimmune diseases

The central role of Syk in signaling processes is not only in cells of immune responses but also in cell types known to be involved in the expression of tissue pathology in autoimmune, inflammatory and allergic

diseases. Therefore, interfering with Syk could represent a possible therapeutic approach for treating these disorders. Indeed, several studies have highlighted Syk as a key player in the pathogenesis of a multitude of diseases, including rheumatoid arthritis, systemic lupus erythematosus and multiple sclerosis.

# Syk, a target for oncology

In hematological cancer, we believe Syk is a high potential target. In hematopoietic cells, Syk is recruited to the intracellular membrane by activated membrane receptors like B-cell receptors or another receptor called Fc and then binds to the intracellular domain of the receptors. Syk is activated after being phosphorylated by Src family kinases and then further induces downstream intracellular signals including B-cell linker, PI3K $\delta$ , BTK and Phospholipase C $\gamma$ 2 to regulate B-cell proliferation, growth, differentiation, homing, survival, maturation, and immune responses. Syk not only involves the regulation of lymphatic cells but also signal transduction of non-lymphatic cells such as mast cells, macrophages, and basophils, resulting in different immunological functions such as degranulation to release immune active substances, leading to immunological reaction and disease. Therefore, regulating B-cell signal pathways through Syk is expected to be effective for treating lymphoma.

The high efficacy and successful approvals of both Imbruvica (ibrutinib) (developed by AbbVie Inc.), a BTK inhibitor, and Zydelig (idelalisib) (developed by Gilead), a PI3Kô inhibitor, are evidence that modulation of the B-cell signaling pathway is critical for the effective treatment of B-cell malignancies. Syk is upstream of both BTK and PI3Kô, and we believe it could deliver the same outcome as Imbruvica and Zydelig, assuming no unintentional toxicities are derived from Syk inhibition. Entospletinib (GS-9973), a Syk inhibitor developed by Gilead, reported promising Phase II study results in late 2015 with a nodal response rate of 65% observed in chronic lymphocytic leukemia and small lymphocytic lymphoma. Nodal response is defined as a greater than 50% decrease from baseline in the sum of lymph node diameters. Gilead has also reported that entospletinib demonstrated a nodal response rate of 44.4% in an exploratory clinical study in chronic lymphocytic leukemia patients previously treated with Imbruvica and Zydelig, thereby indicating that Syk inhibition has the potential to overcome resistance to Imbruvica and Zydelig. Takeda reported similarly strong signs of efficacy for their TAK-659 Phase I dose escalation study in lymphoma, which was also published in late 2015.

### **HMPL-523 Research Background**

The threshold of safety for a Syk inhibitor in chronic disease is extremely high, with no room for material toxicity. The failure of fostamatinib in a global Phase III registration study in rheumatoid arthritis provided important insights for us in the area of toxicity. While fostamatinib clearly showed patient benefit in rheumatoid arthritis, a critical proof-of-concept for Syk modulation, it also caused high levels of hypertension which is widely believed to be due to the high levels of off target KDR inhibition. In addition, fostamatinib has also been shown to strongly inhibit the Ret kinase, and in pre-clinical studies it was demonstrated that inhibition of the Ret kinase was associated with developmental and reproductive toxicities.

The requirement for Syk kinase activity in inflammatory responses was first evaluated with fostamatinib, which was co-developed by AstraZeneca/Rigel Pharmaceuticals, Inc. (also called R788, a prodrug of an active Syk inhibitor R406). In June 2013, AstraZeneca announced results from pivotal Phase III clinical trials that fostamatinib statistically significantly improved ACR20 (a 20% improvement from baseline based on the study criteria) response rates of patients inadequately responding to conventional disease-modifying anti-rheumatic drugs and a single anti-TNF $\alpha$  (a key pro-inflammatory cytokine involved in rheumatoid arthritis pathogenesis) antagonist at 24 weeks, but failed to demonstrate statistical significance in comparison to placebo at 24 weeks. As a result, AstraZeneca decided not to proceed.

Fostamatinib was also in trials for B-cell lymphoma and T-cell lymphoma. It demonstrated some clinical efficacy in diffused large B-cell lymphoma patients with an objective response rate of 22%. Entospletinib, a Syk inhibitor developed by Gilead, has features of high potency and good selectivity toward kinases. However, while the Phase II study discussed above showed that it had significant efficacy in patients with chronic lymphocytic leukemia and small lymphocytic lymphoma, its poor solubility and permeability into intestinal epithelial cells resulted in unsatisfactory oral absorption and a great variation of individual drug exposure. In addition, entospletinib shows some inhibition of the CYP3A4, CYP2D6, and CYP1A2 enzymes involved in the metabolism of certain drugs, and therefore their inhibition could increase the risk of drug-to-drug interaction when used in combined therapy.

#### **HMPL-523 Pre-clinical Evidence**

The safety profile of HMPL-523 was evaluated in multiple in vitro and in vivo pre-clinical studies under GLP guidelines and found to be well tolerated following single dose oral administration. Toxic findings were seen in repeat dose animal safety evaluations in rats and dogs at higher doses and found to be reversible. These findings can be readily monitored in the clinical studies and fully recoverable upon drug withdrawal. The starting dose in humans was suggested to be 5 mg. This dose level is approximately 5% of the human equivalent dose extrapolated from the pre-clinical "no observed adverse event levels", which is below the 10% threshold recommended by FDA guidelines.

## In vitro Pharmacology

HMPL-523 is a highly selective Syk inhibitor with an IC<sub>50</sub> of 24  $\pm$  4 nM (n=7) in a Syk kinase enzymatic assay. HMPL-523 has been evaluated in a kinase selectivity panel of 287 kinases and a broad pharmacological panel of 79 targets. We believe, as shown in the chart below, HMPL-523's lack of KDR inhibition will mean a much lower risk of hypertension, which is a major off-target toxicity of R406 in clinical trials.

Figure 19: HMPL-523 kinase selectivity in comparison to R406 (the Syk inhibitor metabolite of fostamatinib). R406 is shown below to be as potent in inhibiting KDR as it is in inhibiting Syk, and significantly more potent in inhibiting FLT3 and Ret.

Selectivity	HMPL-523 IC <sub>50</sub> (nM)	R406 IC <sub>50</sub> (nM)
Syk enzyme	$25 \pm 5 \ (n=10)^{[a]}$	$54 \pm 16 \ (n=10)^{[a]}$
JAK 1,2,3 enzyme	$>300, >300, >300^{[a]}$	120, 30, 480 <sup>[a]</sup>
FGFR 1,2,3	$>3,000, >3,000, >3,000^{[a]}$	$89, 22, 32^{[a]}$
FLT3 enzyme	63 <sup>[a]</sup>	9 <sup>[a]</sup>
LYN enzyme	921 <sup>[a]</sup>	160 <sup>[a]</sup>
Ret enzyme	>3,000[a]	5 <sup>[b]</sup>
KDR enzyme	$390 \pm 38 \; (n=3)^{[a]}$	$61 \pm 2 \ (n=3)^{[a]}$
KDR cell	$5,501 \pm 1,607 \ (n=3)^{[a]}$	$422 \pm 126 \ (n=3)^{[a]}$

Sources: [a]: Chi-Med, Eun-ho Lee et al, 2011 American College of Rheumatology; [b]: S. P. McAdoo and F. W. Tam, Drugs Future, 2011, 36(4), PP273-283

In vivo Pharmacology

HMPL-523 blocked B-cell activation in mouse whole blood and rat whole blood  $ex\ vivo$  challenge with an EC<sub>50</sub> of 1301 ng/mL (ED<sub>50</sub> of 2.9 mg/kg) and 332.8~471.7 ng/mL (ED<sub>50</sub> of 4.1~5.2 mg/kg) at 2 hours after dosing, respectively. The maximum inhibition was observed at 2 hours after oral dosing, while the significant inhibition was maintained for up to 4 hours.

HMPL-523 was further evaluated in collagen-induced rheumatoid arthritis in mice and rats. HMPL-523 treatment significantly reduced disease severity in a dose dependent manner with an estimated ED<sub>50</sub> of 4.0 - 6.8 mg/kg once daily in mouse collagen-induced arthritis, and suppressed paw swelling with an ED<sub>50</sub> of 1.4 - 2.0 mg/kg once daily in the rat collagen-induced arthritis model (AUC<sub>0-24h</sub> was 1408 h\*ng/mL) and with the minimum efficacious dose (ED<sub>min</sub>) of 0.7 - 1.0 mg/kg once daily (AUC<sub>0-24h</sub> was 413 h\*ng/mL).

HMPL-523 not only halted disease progression, but also reversed aspects of the disease such as paw swelling and bone resorption to normal levels at higher doses in rat collagen-induced arthritis therapeutic models. Figure 20 below shows that HMPL-523 significantly reduced bone resorption at 3 mg/kg once daily dose. The 3 mg/kg once daily HMPL-523 dose delivered similar efficacy to both fostamatinib, at a significantly higher dosage of 10 mg/kg twice daily, and Enbrel (etanercept) (an approved monoclonal antibody from Amgen/Pfizer/Takeda), at the higher dosage of 10 mg/kg once every other day.

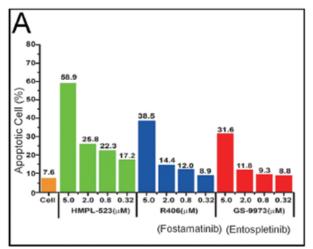
However, at the 10 mg/kg once daily dose, HMPL-523 reached maximum efficacy, which correlated with significant reduction of pro-inflammatory cytokines and chemokines in the joint lavage fluid of rats with collagen-induced arthritis, resulting in an almost total reversal of symptoms in the induced rheumatoid arthritis rat model.

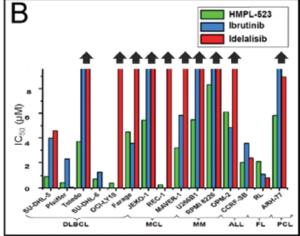
In vivo efficacy of the orally active HMPL-523 was evaluated in lupus-prone (MRL/lpr) mice. HMPL-523, at 20 mg/kg, significantly blocked skin lesions, delayed the onset of proteinuria (the presence of abnormal quantities of proteins in urine which may indicate kidney damage) and reduced the immune organs to body weight ratios and suppressed production of anti-dsDNA antibodies (a group of anti-nuclear antibodies that act against certain DNA).

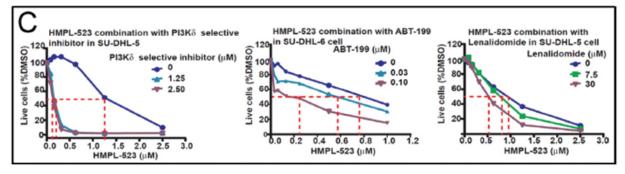
Anti-tumor activity and combination synergy with other therapies

In *in vitro* B-cell lymphoma cell lines with Syk/BCR dysregulation, HMPL-523 was found to block phosphorylation of B-cell linker protein as well as inhibit cell viability by inhibiting cell survival and increasing apoptotic rate. HMPL-523 also showed synergistic anti-tumor activity on human diffused large B-cell lymphoma cells, in combination with other drugs such as PI3Kδ inhibitors, B-cell lymphoma 2 family inhibitors, or chemotherapies. Potent anti-tumor activity was also demonstrated in nude mice bearing B-cell lymphoma xenograft tumors with Syk/B-cell receptor dysregulation.

Figure 20: HMPL-523 in hematological malignancies. Pre-clinical superiority versus both BTK/PI3Kδ tyrosine kinase inhibitors as well as entospletinib (GS-9973)







- A. Syk inhibitors all showed a dose dependent increase in apoptotic rate (cell death) in REC-1 cells with HMPL-523 efficacy stand-out.
- B. HMPL-523 inhibited cells survival in panel of human lymphoma & leukemia cells—standout efficacy versus ibrutinib (BTK) & idelalisib (PI3Kδ) inhibitors.
- C. Combination of HMPL-523 with other drugs (PI3K\dagger tyrosine kinase inhibitor; ABT-199; Lenalidomide) promote cell killing in DLBCL through inducing apoptosis.

### HMPL-523 Current Clinical Development and Near-Term Plans

As discussed below, we currently have various clinical trials of HMPL-523 ongoing or expected to begin in the near term in Australia, the United States and China.

We have been in a Phase I clinical trial in Australia with HMPL-523 since mid-2014 and have completed 10 cohorts of a single ascending dose program in healthy volunteers. In mid-2015, we began a multiple ascending dose study in healthy volunteers, and we successfully completed the multiple dose section of this Phase I study in October 2015. In parallel with this study, we initiated a second Phase I clinical study in Australia in patients with hematological malignancies in January 2016.

Phase I study of HMPL-523 in healthy volunteers in Australia and China (Target Patient Populations 30 and 31 in pipeline chart; Status: complete; NCT02105129)

In November 2016, we reported results of the Phase I dose-escalation study on HMPL-523 in healthy volunteers in Australia, in which a total of 118 adult male healthy subjects were enrolled at baseline and 114 (96.6%) subjects completed the study. The Phase I study showed HMPL-523 exhibited a tolerable safety profile. A total of 83 treatment emergent adverse events were reported, with 38.9% in the HMPL-523 groups and 32.1% in the placebo groups, respectively. Two serious adverse events were reported in the Phase I study and when HMPL-523 was discontinued in those subjects the serious adverse events were resolved. Off-target toxicities such as diarrhea and hypertension, seen with the first-generation Syk inhibitor fostamatinib, were not observed.

In an ex-vivo human whole blood pharmacodynamic assay, HMPL-523 inhibited anti-IgE-induced basophil activation (CD63+) in a concentration-dependent manner with an estimated half maximal effective concentration of 47.70mg/mL. Systemic exposure of HMPL-523 was increased up to 1.5 fold when administered in a fed condition compared to a fasted condition, indicating that food consumption increases the relative bioavailability of HMPL-523. Human pharmacokinetic exposures at 200 mg once daily and above can be expected to provide the target coverage required for clinical efficacy based on the pre-clinical human pharmacokinetic/pharmacodynamics analysis and as a result, a multiple-dose regimen of 300 mg or less of HMPL-523, administered once daily, is the recommended Phase II dose for clinical trials in autoimmune diseases. HMPL-523 demonstrated a dose dependent suppression of B-cell activation. The data were presented at the annual meeting of the American College of Rheumatology/Association of Rheumatology Health Professionals in 2016. We have submitted IND applications for autoimmune diseases and expect, pending the imminent submission of additional data requested by the FDA, to progress into a Phase II proof-of-concept study in immunology in late 2018 or early 2019.

Phase I study of HMPL-523 in hematological cancer—Australia/China (Target Patient Populations 32 and 33 in pipeline chart; Status: enrolling; NCT02503033/NCT02857998)

In early 2016, we initiated a Phase I dose escalation study of HMPL-523 in Australia in hematological cancer patients and have completed seven dose cohorts. The Phase I study in China began in early 2017 and has now completed five dose cohorts. In both Australia and China, we have established both efficacious once daily and twice daily dose regimens. We are now in the process of increasing the number of clinical sites in Australia and China to support Phase Ib/II expansion in a broad range of indolent non-Hodgkin's lymphoma sub-types. We target to present dose escalation and expansion results, including preliminary proof-of-concept data, at a major scientific conference later in 2018.

### HMPL-689 PI3Ko Inhibitor

HMPL-689 is a novel, highly selective and potent small molecule inhibitor targeting the isoform PI3K $\delta$ , a key component in the B-cell receptor signaling pathway. We have designed HMPL-689 with superior PI3K $\delta$  isoform selectivity, in particular to not inhibit PI3K $\gamma$  (gamma), offering advantages over Zydelig to minimize the risk of serious infection caused by immune suppression. HMPL-689's strong potency, particularly at the whole blood level, also allows for reduced daily doses to minimize compound related toxicity, such as the high level of liver toxicity observed with the first-generation PI3K $\delta$  inhibitor Zydelig. HMPL-689's pharmacokinetic properties have been found to be favorable with good oral absorption, moderate tissue distribution and low clearance in pre-clinical pharmacokinetic studies. We also expect that HMPL-689 will have low risk of drug accumulation and drug-to-drug interaction.

Given this, we believe that HMPL-689 has the potential to be a global best-in-class PI3Kδ agent. We currently retain all rights to HMPL-689 worldwide.

#### **Mechanism of Action**

Class I phosphatidylinositide-3-kinases, or PI3Ks, are lipid kinases that, through a series of intermediate processes, control the activation of several important signaling proteins including the serine/threonine kinase AKT. In most cells, AKT is a key PI3K effector that regulates cell proliferation, carbohydrate metabolism, cell motility and apoptosis, and other cellular processes. Please refer to Figure 18 ("The B-cell signaling pathway").

There are multiple sub-families of PI3K kinases, and PI3Kδ plays important roles in B-cell activation, development, survival and migration. PI3Kδ is mainly expressed in circulating leukocytes and lymphoid tissues and plays critical roles in B-cell activation and proliferation. PI3Kδ is the central signaling enzyme that mediates the effects of multiple receptors on B-cells. Upon an antigen binding to B-cell receptors, PI3Kδ can be activated through the Lyn and Syk signaling cascade.

Aberrant B-cell function has been observed in multiple autoimmune diseases and B-cell mediated malignancies. Therefore, PI3Kδ is considered to be a promising target for drugs that aim to prevent or treat hematologic cancer, autoimmunity and transplant organ rejection and other related inflammation diseases.

#### **HMPL-689 Pre-clinical Evidence**

Compared to other PI3Kô inhibitors, HMPL-689 shows higher potency and selectivity.

Figure 21: Enzyme selectivity (IC<sub>50</sub>, in nM) of HMPL-689 versus competing PI3Kδ inhibitors; this shows HMPL-689 is approximately five-fold more potent than Zydelig (idelalisib) on whole blood level and, unlike duvelisib, does not inhibit PI3Kγ.

IC <sub>50</sub> (nM)	HMPL-689	idelalisib	duvelisib
Pl3K₀	0.8 (n=3)	2	1
PI3K <sub>γ</sub> enzyme level (fold vs.PI3K <sub>δ</sub> )	114 (142x)	104 (52x)	2 (2x)
PI3Kα enzyme level (fold vs.PI3Kδ)	>1,000 (>1,250x)	866 (433x)	143 (143x)
Pl3K₅ human whole blood CD63+	3	14	15
Pl3Kβ enzyme level (fold vs.Pl3Kε)	87 (109x)	293 (147x)	8 (8x)

Source: Chi-Med

#### **HMPL-689 Clinical Development**

Phase I dose escalation study of HMPL-689—Australia and China (Target Patient Populations 34 and 35 in pipeline chart; Status: enrolling; NCT02631642/NCT03128164)

In 2016, we completed a Phase I, first-in-human, dose escalation study in healthy adult volunteers in Australia to evaluate the pharmacokinetics and safety profile following single oral dosing HMPL-689. Results were as expected with linear pharmacokinetics properties and good safety profile.

We subsequently received IND clearance in China and then initiated a Phase I dose escalation and expansion study in patients with hematologic malignancies in August 2017.

#### HMPL-453 FGFR Inhibitor

### Mechanism of Action

Fibroblast growth factor receptors, or FGFRs, belong to a subfamily of receptor tyrosine kinases, or RTKs. Four different FGFRs (FGFR1-4) and at least 18 ligand FGFs constitute the FGF/FGFR signaling system. Activation of the FGFR pathway through the phosphorylation of various downstream molecules ultimately leads to increased cell proliferation, migration and survival. FGF/FGFR signaling regulates a wide range of basic biological processes, including tissue development, angiogenesis, and tissue regeneration. Given the inherent complexity and critical roles in physiological processes, dysfunction in the FGF/FGFR signaling leads to a number of developmental disorders and is consistently found to be a driving force in cancer. Deregulation of the FGFR can take many forms, including receptor amplification, activating mutations, gene fusions, and receptor isoform switching, and the molecular alterations are found at relatively low frequencies in most tumors. The incidence of FGFR aberrance in various cancer types is listed in Figure 22 below.

Figure 22: Common genetic alterations in FGFRs related to cancer

Gene	Cancer type (incidence)
FGFR1	
Amplification	Lung squamous cell (7-15%), Head and neck squamous (10-17%), Esophageal squamous carcinoma (9%), Small cell lung (6%), Osteosarcoma (17%), Breast (10-15%), Ovarian (5%)
Mutation	Pilocytic astrocytoma (5%–8%), Gastric cancer (4%)
Translocation	Glioblastoma (na), Breast cancer (na), Lung squamous cell carcinoma (na)
FGFR2	
Amplification	Gastric cancer (5%–10%), Breast cancer (4%)
Mutation	Endometrial cancer (12%–14%), Lung squamous cell carcinoma(5%)
Translocation	Intrahepatic cholangiocarcinoma (14%), Prostate cancer (na), Breast cancer (na)
FGFR3	
Amplification	Bladder carcinoma (na), Salivary adenoid cystic cancer (na)
Mutation	Bladder carcinomas (60%–80% in non-muscle-invasive, 15–20% in muscle-invasive), Cervical cancer (5%)
Translocation	Bladder carcinoma (3%–6%), Glioblastoma (3%), Myeloma (15%–20%), Lung adenocarcinoma (0. 5%), Lung squamous cell carcinomas (3%), Head and neck (na)
FGFR4	
Mutation	Rhabdomyosarcoma (6%–8%)

Source: M. Touat et al, "Targeting FGFR Signaling in Cancer," Clinical Cancer Research (2015); 21(12); 2684-94

### HMPL-453 Research Background

We noted a growing body of evidence has demonstrated the oncogenic potential of FGFR aberrations in driving tumor growth, promoting angiogenesis, and conferring resistance mechanisms to anti-cancer therapies. Targeting the FGF/FGFR signaling pathway has therefore attracted a good deal of attention from biopharmaceutical companies and has become an important exploratory target for new anti-tumor target therapies.

Currently, FGFR monoclonal antibodies, FGF ligand traps and small molecule FGFR tyrosine kinase inhibitors are being evaluated in early clinical studies. BGJ-398 (Novartis), AZD4547 (AstraZeneca) and JNJ-42756493 (Johnson & Johnson) are the leading FGFR selective tyrosine kinase inhibitors, and their early clinical trials provided substantial proof-of-concept with regard to anti-tumor efficacy and pharmacodynamic markers of effective FGFR pathway inhibition.

The main FGFR on-target toxicities observed to date in these compounds are all mild and manageable, including hyperphosphatemia, nail and mucosal disorder, and reversible retinal pigmented epithelial detachment. However, there are still many challenges in the development of FGFR-directed therapies. Uncertainties include the screening and stratifying of patients who are most likely to benefit from FGFR targeted therapy. Intra-tumor heterogeneity observed in FGFR amplified cancer may compromise the anti-tumor activity. In addition, the low frequency of specific FGFR molecular aberrance in each cancer type may hinder clinical trial enrollment. As a result, there have been no approved therapies specifically targeting the FGFR signaling pathway to date.

### **HMPL-453 Pre-clinical Evidence**

HMPL-453 is a potential first-in-class novel, highly selective and potent, small molecule that targets FGFR 1/2/3 with an IC<sub>50</sub> in the low nanomolar range. Its good selectivity was revealed in the screening against 292 kinases. HMPL-453 exhibited strong anti-tumor activity that correlated with target inhibition in tumor models with abnormal FGFR activation.

HMPL-453 has good pharmacokinetic properties characterized by rapid absorption following oral dosing, good bioavailability, moderate tissue distribution and moderate clearance in all pre-clinical animal species. HMPL-453 was found to have little inhibitory effect on major cytochrome P450 enzymes, indicating low likelihood of drug-to-drug interaction issues.

# **HMPL-453 Clinical Development**

Phase I dose escalation study of HMPL-453 in solid tumors—Australia and China (Target Patient Populations 36 and 37 in pipeline chart; Status: enrolling; NCT02966171/NCT03160833)

In June 2017, we initiated a Phase I/II clinical trial of HMPL-453 in China. This Phase I/II study is a multi-center, single-arm, open-label, two-stage study to evaluate safety, tolerability, pharmacokinetics and preliminary efficacy of HMPL-453 monotherapy in patients with solid tumors harboring FGFR genetic alterations. The dose-escalation stage will enroll patients with locally advanced or metastatic solid tumors, for whom standard therapy either does not exist or has proven to be ineffective or intolerable, regardless genetic status, to determine the maximum tolerated dose and recommended Phase II dose. The dose-escalation will be followed by a dose-expansion stage, which will further evaluate safety, tolerability and pharmacokinetics as well as preliminary anti-tumor efficacy at the recommended Phase II dose. This stage will enroll primarily cancer patients harboring FGFR dysregulated tumors, including those with advanced bladder cancer, advanced cholangiocarcinoma and other solid tumors. For this second stage, the primary endpoint is objective response rate, with secondary endpoints including duration of response, disease control rate, progression-free survival, overall survival and safety.

This study complements the first-in-human Phase I clinical trial in Australia that was initiated in February 2017. The first-in-human dose-escalation trial aims to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of HMPL-453 in patients with advanced or metastatic solid malignancies, who have failed or are unable to tolerate standard therapies or for whom no standard therapies exist. This open-label study consists of two preliminary phases, a dose-escalation (stage 1) and a dose-expansion stage (stage 2).

#### HMPL-004/HM004-6599 Botanical NF-kB Modulator

In November 2012, we established Nutrition Science Partners, a joint venture with Nestlé Health Science. The purpose of Nutrition Science Partners is to develop, manufacture and commercialize HMPL-004 for ulcerative colitis and Crohn's disease and to identify, develop, manufacture and commercialize products in gastrointestinal indications.

We have worked with Nestlé Health Science to prepare an IND application for HM004-6599, which was submitted in China in March 2017, and to prepare for a Phase I study of HM004-6599 in Australia in 2018. HM004-6599 is an enriched / purified re-formulation of HMPL-004, our drug candidate that reported positive Phase II results in ulcerative colitis in 2010 but then went on to prove futile in an interim analysis of the subsequent Phase III study in 2014. HM004-6599 has a higher level of biologically active components and improved manufacturing control, as compared to HMPL-004.

For more information regarding our partnership with Nestlé Health Science, see "—Overview of Our Collaborations."

# HMPL-004/HM004-6599 Research Background

HMPL-004, and the newer, enriched version HM004-6599 discussed below, are proprietary botanical drugs for the treatment of inflammatory bowel diseases, namely ulcerative colitis and Crohn's disease.

The current standard of care for inflammatory bowel disease starts with 5-aminosalicylic acids, or 5-ASA, which can induce and maintain clinical response and remission in an average of approximately 50% of inflammatory bowel disease patients. For the 5-ASA non-responding patients with moderate-to-severe active diseases, various forms of corticosteroids and immunosuppressant drugs and anti-tumor necrosis factor agents such as biologics are prescribed. These agents, though effective, are associated with many side effects, sometimes serious, and are not often suitable for prolonged usage.

Accordingly, there remain clear unmet medical needs for new therapies which can induce and maintain remission among 5-ASA non-responding or intolerant patients, and the need for safer agents without the side effects of corticosteroids and immune suppressors.

## **HMPL-004 Pre-clinical Evidence**

Extensive pre-clinical studies indicated that HMPL-004 exhibits its anti-inflammatory effects through the inhibition of multiple cytokines (proteins), such as NF-kB (a protein complex that controls transcription of DNA, cytokine production and cell survival), both systemically and locally, which are involved in causing digestive tract inflammation. HMPL-004's efficacy, when combined with 5-ASAs, in induction of clinical response, remission and healing of the mucosa (a mucous membrane lining the intestine), as well as a favorable safety profile has been established in multiple clinical trials, including a successful global Phase IIb study in mild-to-moderate ulcerative colitis patients.

## HMPL-004 Early and Completed Clinical Development

As discussed below, we have completed various clinical trials of HMPL-004 in the United States, Canada, Europe and Ukraine.

Phase IIb ulcerative colitis trial

The Phase IIb ulcerative colitis trial was a multi-center, double-blind, randomized and placebo-controlled study conducted in 223 ulcerative colitis patients in the United States, Canada and Europe. Results were reported in November 2009. The three-arm clinical trial included eight week treatment with HMPL-004 at two dose levels, 1,200 mg per day or 1,800 mg per day, as compared to placebo. Completed data analysis demonstrated that all primary and key secondary endpoints were achieved. There were no

treatment-related serious adverse events in either of the HMPL-004 arms reported by the investigators. Importantly, clinical efficacy, including response, remission, and mucosal healing, improved markedly as dose increased among the intent-to-treat patient population, with the higher 1,800 mg dose outperforming the 1,200 mg dose and placebo in all areas. The clinical response of the 1,800 mg arm was 71% (p = 0.0003) compared to 48% (p = 0.17) for the 1,200 mg arm and 35% for placebo. Remission of the 1,800 mg arm was 39% (p = 0.013) compared to 32% (p = 0.08) for the 1,200 mg arm and 17% for placebo. Mucosal healing of the 1,800 mg arm was 53% (p = 0.007) compared to 38% (p = 0.23) for the 1,200 mg arm and 27% for placebo. This trial was recognized as the Distinguished Abstract Plenary oral presentation at Digestive Disease Week in 2010, which is a distinguished honor in the global gastrointestinal disease field.

## Phase II Crohn's disease trial

The Phase II Crohn's disease trial was a multi-center, double-blind, randomized, and placebo-controlled study conducted in 101 Crohn's disease patients in the United States and Ukraine. Results were reported in July 2009. The two-arm clinical trial demonstrated a clear trend of efficacy for HMPL-004 at the 1,200 mg per day dose level with no treatment-related serious adverse events. Clinical response of the 1,200 mg arm was 37% (p = 0.087) versus 22% for placebo. Remission of the 1,200 mg arm was 29% (p = 0.069) versus 14% for placebo.

## NATRUL-3 global Phase III ulcerative colitis registration trial

In April 2013, Nestlé Health Science initiated the NATRUL-3 global Phase III registration trial in mild-to-moderate ulcerative colitis patients on HMPL-004, in combination treatment with 5-ASAs, and conducted an interim analysis in mid-August 2014. The interim analysis was intended to assess both futility, in terms of efficacy and safety on approximately one-third of the 420 planned patients in NATRUL-3. The result of the interim analysis was that HMPL-004 showed no overall material effect over the placebo-arm patients and consequently the NATRUL-3 study was terminated and the data un-blinded.

Subsequent post-hoc analysis of the un-blinded NATRUL-3 data indicates an efficacy signal among the 51% of NATRUL-3 patients who had been on 5-ASAs for more than one year prior to enrollment. These patients at the time of their enrollment in NATRUL-3 were in ulcerative colitis flare condition and as such could be considered as 5-ASA non-responders. The efficacy signal was further enhanced among these 5-ASA non-responders when patients with difficult-to-treat concurrent medical conditions, that could have affected ulcerative colitis response, were removed.

In summary, we believe the above clinical data demonstrates clinical efficacy for HMPL-004, with 5-ASA resistant/non-responding patients benefiting the most. Furthermore, HMPL-004's formulation contains almost 80% inactive substances, which leads to a heavy pill burden and patient compliance challenges. During 2015, we focused on optimizing the HMPL-004 formulation by adding several steps to the extraction process and thereby increasing the concentration of diterpenoids, the key bioactive ingredient of HMPL-004. The new enriched formulation of HMPL-004, which we have named HM004-6599, is now over 70% diterpinoids as compared to the original formulation which comprised approximately 15% diterpenoids. In extensive pre-clinical in-vitro models, HM004-6599 has demonstrated superior inhibition of NF-kB activation, pro-inflammatory cytokine IL-1β (an important mediator in the regulation of immune and regulatory responses to infections) production and TNFα inhibitors dependent chemokine production including the CCL-20 cytokine. Given the enrichment, the predicted human dose of HM004-6599 could be as low as 400 mg to 800 mg daily versus the 2,400 mg daily usage of HMPL-004.

In the first half of 2017, we submitted our IND application for HM004-6599 in China and we now await clearance to proceed into Phase I clinical studies. We also target to initiate Phase I clinical studies in Australia in 2018.

Nutrition Science Partners has additional gastrointestinal drug candidates in research and pre-clinical development.

### **Overview of Our Collaborations**

Collaborations and joint ventures with corporate partners have provided us with significant funding and access to our partners' scientific, development, regulatory and commercial capabilities. Our current collaborations focus on savolitinib (collaboration with AstraZeneca), fruquintinib (collaboration with Eli Lilly) and HMPL-004/HM004-6599 (collaboration with our joint venture partner Nestlé Health Science). Our collaboration partners fund a significant portion of our research and development costs for drug candidates developed in collaboration with them. In addition, we receive upfront payments upon our entry into these collaboration arrangements and upon the achievement of certain development milestones for the relevant drug candidate. We and Nutrition Science Partners, in the aggregate, have received upfront payments, equity contributions and milestone payments totaling approximately \$135.5 million mainly from our collaborations with AstraZeneca, Eli Lilly, Nestlé Health Science as of December 31, 2017. We and Nutrition Science Partners, in the aggregate, may potentially receive up to \$340.0 million in future development and approval milestones, \$145.0 million in option payments and \$560.0 million in commercial milestones in the aggregate. In return, our collaboration partners are entitled to a significant proportion of any future revenue from our drug candidates developed in collaboration with them, as well as a degree of influence over the clinical development process for such drug candidates.

### AstraZeneca

In December 2011, we entered into an agreement with AstraZeneca under which we granted to AstraZeneca co-exclusive, worldwide rights to develop, and exclusive worldwide rights to manufacture and commercialize savolitinib for all diagnostic, prophylactic and therapeutic uses. We refer to this agreement as the AstraZeneca Agreement. AstraZeneca paid \$20.0 million upon execution of the AstraZeneca Agreement and agreed to pay royalties and additional amounts upon the achievement of development and sales milestones. Under the original terms of the AstraZeneca Agreement, we and AstraZeneca agreed to share the development costs for savolitinib in China, with AstraZeneca being responsible for the development costs for savolitinib in the rest of the world. Based on savolitinib showing early clinical benefit as a highly selective c-Met inhibitor in a number of cancers, in August 2016 we and AstraZeneca amended our global licensing, co-development, and commercialization agreement for savolitinib whereby we agreed to contribute up to \$50 million, spread primarily over three years, to the joint development costs of the global pivotal Phase III study in patients with c-Met driven papillary renal cell carcinoma. As of December 31, 2017, we had received \$24.9 million in milestone payments in addition to approximately \$19.4 million in reimbursements for certain development costs. We may potentially receive future clinical development and first sales milestones payments of up to \$95.0 million for clinical development and initial sales of savolitinib, plus significant further milestone payments based on sales. AstraZeneca also reimburses us for certain development costs. Subject to approval of savolitinib in papillary renal cell carcinoma, under the amended AstraZeneca Agreement, AstraZeneca is obligated to pay us increased tiered royalties from 14.0% to 18.0% annually on all sales made of any product outside of China, which represents a five percentage point increase over the original terms. After total aggregate sales of savolitinib have reached \$5 billion, this royalty will step down over a two year period, to an ongoing royalty rate of 10.5% to 14.5%. AstraZeneca is also obligated to pay us a fixed royalty of 30.0% on all sales made of any product in China.

Development and collaboration under this agreement are overseen by a joint steering committee that is comprised of three of our senior representatives as well as three senior representatives from AstraZeneca. AstraZeneca is responsible for the development of savolitinib and all regulatory matters related to this agreement in all countries and territories other than China, and we are responsible for the development of savolitinib and all regulatory matters related to this agreement in China.

Subject to earlier termination, the AstraZeneca Agreement will continue in full force and effect on a country-by-country basis as long as any collaboration product is being developed or commercialized. The AstraZeneca Agreement is terminable by either party upon a breach that is uncured, upon the occurrence

of bankruptcy or insolvency of either party, or by mutual agreement of the parties. The AstraZeneca Agreement may also be terminated by AstraZeneca for convenience with 180 days' prior written notice. Termination for cause by us or AstraZeneca or for convenience by AstraZeneca will have the effect of, among other things, terminating the applicable licenses granted by us. Termination for convenience by AstraZeneca will have the effect of obligating AstraZeneca to grant to us all of its rights to regulatory approvals and other rights necessary to commercialize savolitinib. Termination by AstraZeneca for convenience will not have the effect of terminating any license granted by AstraZeneca to us.

### Eli Lilly

## Eli Lilly Agreement

In October 2013, we entered into an agreement with Eli Lilly whereby we grant Eli Lilly an exclusive license to develop, manufacture and commercialize fruquintinib for all uses in China and Hong Kong. We refer to this agreement as the Eli Lilly Agreement. Eli Lilly paid a \$6.5 million upfront fee following execution of the Eli Lilly Agreement, and agreed to pay royalties and additional amounts upon the achievement of development and regulatory approval milestones. As of December 31, 2017, Eli Lilly had paid us \$23.7 million in milestone payments in addition to approximately \$38.1 million in reimbursements for certain development costs. We may potentially receive future milestone payments of up to \$55.0 million for the achievement of development and regulatory approval milestones in China and additional milestone payments of up to \$300.0 million for the achievement of development, regulatory approval and commercial milestones in other jurisdictions if Eli Lilly exercises its option to develop fruquintinib in such other jurisdictions. See "—Eli Lilly Option Agreement" for further discussion of Eli Lilly's option to develop fruquintinib globally. Additionally, Eli Lilly is obligated to pay us tiered royalties from 15.0% to 20.0% annually on sales made of fruquintinib in China and Hong Kong, the rate to be determined based upon the dollar amount of sales made for all products in that year.

Development, collaboration and manufacture of products under this agreement are overseen by a joint steering committee comprised of equal numbers of representatives from each party. We are responsible for all development activities for fruquintinib.

We are responsible for all development costs in relation to fruquintinib in the following indications: third-line colorectal cancer, third-line non-small cell lung cancer and second-line advanced gastric cancer, until fruquintinib has achieved proof-of-concept. After achieving proof-of-concept for any such indication, Eli Lilly will be responsible for a majority of subsequent development costs.

Once development is complete, Eli Lilly is obligated to use commercially reasonable efforts to commercialize products and bears all the costs and expenses incurred in such commercialization efforts.

We are responsible in consultation with Eli Lilly for the supply of, and have the right to supply, all clinical and commercial supplies for fruquintinib pursuant to an agreed strategy for manufacturing. For the term of the Eli Lilly Agreement, such supplies will be provided by us at a transfer price that accounts for our cost of goods sold.

The Eli Lilly Agreement is terminable by either party for breach that is uncured. The Eli Lilly Agreement is also terminable by Eli Lilly for convenience with 120 days' prior written notice or if there is a major unexpected safety issue with respect to a product. Termination by either us or Eli Lilly for any reason will have the effect of, among other things, terminating the applicable licenses granted by us, and will obligate Eli Lilly to transfer to us all regulatory materials necessary for us to continue development efforts for fruquintinib.

# Eli Lilly Option Agreement

In addition, we have entered into an option agreement with Eli Lilly and Company, under which Eli Lilly and Company can choose to include additional countries in the territory for development and

commercialization of fruquintinib. The amount payable by Eli Lilly and Company to exercise the option is variable and depends upon the stage of development at which Eli Lilly and Company chooses to exercise its option. Additionally, we are eligible for milestone and royalty payments based on the territory where the option is exercised and the annual dollar amount of sales of a product.

### Nestlé Health Science

Nutrition Science Partners Joint Venture Agreement

In November 2012, we entered into a joint venture agreement with Nestlé Health Science to form Nutrition Science Partners, a joint venture whose shares are owned in equal portions by us and Nestlé Health Science. The objective of Nutrition Science Partners is to develop, manufacture and commercialize HMPL-004/HM004-6599 for ulcerative colitis and Crohn's Disease and to identify, develop, manufacture and commercialize products in gastrointestinal indications. Upon execution of the joint venture agreement, Nestlé Health Science paid \$30.0 million in exchange for its 50% of the equity in Nutrition Science Partners. We provided payment-in-kind by contributing global development and commercial rights to the HMPL-004/HM004-6599 compound and certain exclusive rights to our botanical library, among other things, to the joint venture for our 50% of the equity. Nutrition Science Partners may potentially receive future milestones payments of up to \$150.0 million.

Neither we nor Nestlé Health Science was permitted to sell, transfer or otherwise dispose of our ownership in Nutrition Science Partners until November 27, 2016 without the other's prior written consent. After this lock-up period, if either we or Nestlé Health Science wish to sell, transfer or otherwise dispose of our or its shares, the other has a right of first refusal to purchase all, but not some, of the other's shares. Each of us is entitled to receive dividends from Nutrition Science Partners as approved by the board. To date, we have not received dividends from Nutrition Science Partners. We and Nestlé Health Science are responsible for providing additional funding required by Nutrition Science Partners in proportion to each of our ownership percentages. During 2016, we and Nestlé Health Science agreed to waive \$7.0 million each in loans to Nutrition Science Partners, and each party capitalized the outstanding amount as share capital. Additionally, in 2016 we provided \$5.0 million in share capital to Nutrition Science Partners, with Nestlé Health Science providing the same amount. In February 2017, we and Nestlé Health Science each contributed an additional \$7.0 million share capital funding to Nutrition Science Partners.

The operations of Nutrition Science Partners are overseen by its shareholders and board of directors. The board of directors consists of eight directors, with four directors nominated by each of Nestlé Health Science and ourselves.

### Nutrition Science Partners Services Agreement

In March 2013, we also entered into a services agreement with Nutrition Science Partners to provide research and development services to Nutrition Science Partners, including: (i) collection, monitoring, processing and distribution of adverse event reports and safety and medical information including side-effects; (ii) development of manufacturing and analytical technologies for HMPL-004 raw materials; (iii) quality control and assurance of product manufacturing management; and (iv) ongoing discovery research and non-clinical support for the development of HMPL-004/HM004-6599.

This services agreement is terminable by either party upon an uncured material breach or immediately upon the other party's bankruptcy and by Nutrition Science Partners for convenience with 90 days' prior written notice. If Nutrition Science Partners terminates for convenience, it will be required to pay all of our non-cancellable costs.

## Nutrition Science Partners Research and Collaboration Agreement

In March 2013, we also entered into a research and collaboration agreement with Nestlé Health Science and Nutrition Science Partners to develop new products with impact on gastrointestinal disorders and diseases of the gastrointestinal tract to the proof-of-concept stage. We are obligated, as is Nestlé Health Science, to use commercially reasonable efforts to conduct the activities designated to us and Nestlé Health Science respectively to achieve these research and development goals. We are entitled to compensation for performance under this agreement on the basis of the number of our full-time employees who perform research and development activities. For the years ended December 31, 2015, 2016 and 2017, we received approximately \$5.1 million, \$8.1 million and \$8.9 million, respectively, for the provision of these research and development services to Nutrition Science Partners under this agreement and the services agreement discussed above.

Under this research and collaboration agreement, we have granted to Nutrition Science Partners an initial exclusivity period lasting until December 31, 2022. The exclusivity period will be automatically extended for further one-year periods provided Nutrition Science Partners meets certain budgetary and expenditure criteria. During the exclusivity period, we are obligated not to perform research for ourselves or third parties, or grant to any third parties the right to research or develop products from, or derived from, our botanical library that could be developed for treating gastrointestinal disorders and/or disease of the gastrointestinal tract. Research and collaboration under this agreement will be overseen by a research collaboration subcommittee of the board of directors of Nutrition Science Partners, comprised of equal numbers of representatives from us and Nestlé Health Science.

This research and collaboration agreement is terminable by any party for an uncured material breach of any other party or immediately upon any other party's bankruptcy. It is also terminable by Nutrition Science Partners for convenience with 90 days' prior written notice. If Nutrition Science Partners terminates for convenience, it will be required to pay all of our and Nestlé Health Science's non-cancellable costs.

### Nutrition Science Partners Option Agreement

In March 2013, Nestec Ltd., which is an affiliate of Nestlé Health Science, and Nutrition Science Partners entered into an option agreement under which Nestec Ltd. is eligible to obtain exclusive licenses to commercialize HMPL-004/HM004-6599 products in certain territories. Nestec Ltd. could potentially pay Nutrition Science Partners up to \$70 million in option exercise payments in the aggregate. The option exercise payments are made in one-time payments per territory and the individual amounts vary depending upon the territory for which the option is exercised. Each of these options is terminable by Nestec Ltd. at its convenience.

### **Our Commercial Platform**

Since 2001, we have also developed a profitable Commercial Platform in China, which encompasses two businesses: our Prescription Drugs and Consumer Health businesses. The continuing operations of our Commercial Platform generated \$40.0 million in net income attributable to our company in 2017, which has contributed to the funding of our Innovation Platform's drug development programs.

Our Commercial Platform has grown strongly since we began operations in 2001. In total, net income attributable to our company from the continuing operations of our Commercial Platform was \$25.2 million, \$70.3 million and \$40.0 million for the years ended December 31, 2015, 2016 and 2017, respectively. Net income attributable to our company from our Commercial Platform included one-time gains of \$40.4 million and \$2.5 million in the years ended December 31, 2016 and 2017, respectively, net of tax, from land compensation and other government subsidies paid to Shanghai Hutchison Pharmaceuticals by the Shanghai government.

The infrastructure of our Commercial Platform, particularly in commercial operations management, manufacturing and distribution, regulatory and reimbursement coverage, is well established in our therapeutic specialty areas such as cardiovascular and central nervous system health. In addition to this, in due course we intend to build a dedicated oncology and immunology sales and marketing organization to broaden our therapeutic focus and to prepare for commercialization of drug candidates from our Innovation Platform, if approved. Our Prescription Drugs business is now deploying its network of medical sales representatives to market and sell drugs in China in new therapeutic areas such as for Seroquel which is used to treat psychiatric disorders, which we believe demonstrates the adaptability of our Commercial Platform. As of December 31, 2017, Shanghai Hutchison Pharmaceuticals had a dedicated medical sales team of about 120 people in this new therapeutic area.

## Prescription Drugs Business

Our Prescription Drugs division is conducted through the following two joint ventures in which we nominate management and run the day-to-day operations:

- Shanghai Hutchison Pharmaceuticals, which primarily manufactures, markets and distributes prescription drug products originally contributed by our joint venture partner, as well as third-party prescription drugs. 50% of this joint venture is owned by us and 50% by Shanghai Pharmaceuticals, a leading pharmaceutical company in China listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange, and
- Hutchison Sinopharm, which focuses on providing logistics services to, and distributing and marketing prescription drugs manufactured by, third-party pharmaceutical companies in China. 51% of this joint venture is owned by us and 49% is owned by Sinopharm, a leading distributor of pharmaceutical and healthcare products and a leading supply chain service provider in China listed on the Hong Kong Stock Exchange.

Our Prescription Drugs business employs a physician-targeted marketing model that is focused on promoting its products by providing physicians and hospitals with information on the benefits and differentiating clinical aspects of our products. In collaboration with our partners, we have built our joint ventures' extensive prescription drug sales and distribution network across China, with approximately 2,300 medical sales representatives as of December 31, 2017. These medical sales representatives covered about 22,500 hospitals and about 98,000 physicians in over 300 cities and towns in China as of December 31, 2017. Approximately 66% of these medical sales representatives cover eastern and central-southern China. Of the remaining medical sale representatives, approximately 24% cover northern China and approximately 10% cover western and south-western China.

**Shanghai Hutchison Pharmaceuticals**—manufacturing, marketing and distributing proprietary and licensed prescription drugs

Shanghai Hutchison Pharmaceuticals primarily engages in the manufacture and sale of prescription drug products originally contributed by our joint venture partner, as well as third-party prescription drugs with a focus on cardiovascular medicine. Shanghai Hutchison Pharmaceuticals' proprietary products are sold under the "Shang Yao" brand, literally meaning "Shanghai pharmaceuticals," a trademark that has been used for over 40 years in the pharmaceutical retail market, primarily in Eastern China. As of December 31, 2017, Shanghai Hutchison Pharmaceuticals held 74 registered drug licenses in China, of which 31 are included in the National Medicines Catalogue. In addition, 17 of Shanghai Hutchison Pharmaceuticals' products, of which three are in active production, are represented on China's National Essential Medicines List.

Its key product is She Xiang Bao Xin pills, a vasodilator for the long-term treatment of coronary artery and heart disease and for rapid control and prevention of acute angina pectoris, a form of chest pain, which is listed on China's low price drug list, or LPDL, and fully reimbursed in all provinces in China.

She Xiang Bao Xin pills' sales represented 86% of all Shanghai Hutchison Pharmaceuticals sales in 2017. She Xiang Bao Xin pills accounted for 15.4% of China's rapidly growing botanical coronary artery disease prescription drug market, which is approximately \$2.0 billion in 2017. During late 2016 and early 2017, we were able to effectively implement a pricing strategy that led to a 20.2% growth in second half 2017 sales of Shanghai Hutchison Pharmaceuticals (to \$114.9 million) and materially improved margins. The average daily cost of She Xiang Bao Xin pills is RMB4.00, or approximately \$0.60.

She Xiang Bao Xin pills were first approved in 1983 and subsequently enjoyed 23 proprietary commercial protections under the prevailing regulatory system in China. In 2005, Shanghai Hutchison Pharmaceuticals was able to attain "Confidential State Secret Technology" status protection, as certified by China's Ministry of Science and Technology and State Secrecy Bureau, which extended proprietary protection in China until late 2016, and it is in the process of renewing this protection. Shanghai Hutchison Pharmaceuticals holds an invention patent in China covering its formulation, which extends proprietary protection through 2029.

Prior to September 2016, Shanghai Hutchison Pharmaceuticals manufactured its products at its GMP-certified production facility in Shanghai, which had a site area of approximately 58,000 square meters. In December 2015, it entered into an agreement with the Shanghai government to surrender its land use rights of the property where this facility is located for cash compensation, which has been paid in full. In September 2016, Shanghai Hutchison Pharmaceuticals fully transitioned its 500-person production unit into and began production at its new facility located in Feng Pu district outside the center of Shanghai. The site area of the new facility is approximately 78,000 square meters with three times the production capacity as the old one. The new manufacturing facility cost approximately \$102 million and was financed over the past three years mainly with operating cash flow and limited bank debts. After repayment of bank debts and taxes related to this new facility and the receipt of compensation for the land use rights where the old facility was located, Shanghai Hutchison Pharmaceuticals was able to distribute dividends of \$81.3 million in 2017 equally to us and Shanghai Pharmaceuticals.

Shanghai Hutchison Pharmaceuticals, through its GSP-certified subsidiary, also markets and sells third-party prescription drugs in collaboration with Hutchison Sinopharm. As discussed below, in late 2014 and early 2015, Hutchison Sinopharm signed agreements with Merck Serono and AstraZeneca to provide marketing services for Merck Serono's Concor (a cardiovascular drug) and AstraZeneca's Seroquel (a drug for the treatment of various psychiatric disorders) to market and distribute such drugs in China. In connection with Hutchison Sinopharm's agreements with Merck Serono and AstraZeneca, Hutchison Sinopharm entered into agreements with Shanghai Hutchison Pharmaceuticals to provide certain promotion and marketing services within China for these drugs. Under these agreements, Shanghai Hutchison Pharmaceuticals manages marketing and is paid a fee for its services provided. Hutchison Sinopharm manages distribution and logistics for these products and is paid a fee for its services provided.

Shanghai Hutchison Pharmaceuticals, through its GSP-certified subsidiary, sells its products and its third-party licensed prescription drugs directly to distributors who on-sell such products to hospitals and clinics, pharmacies and other retail outlets in their respective areas, as well as to other local distributors. Its medical sales representatives promote its products to doctors and purchasing managers in hospitals, clinics and pharmacies as part of its marketing efforts. As of December 31, 2017, Shanghai Hutchison Pharmaceuticals had approximately 2,300 medical sales representatives and about 550 manufacturing employees across China.

**Hutchison Sinopharm**—providing logistics services and marketing and distribution primarily for prescription drugs manufactured by third parties

In April 2014, we commenced operating Hutchison Sinopharm, a consolidated joint venture in collaboration with Sinopharm. Based in Shanghai, Hutchison Sinopharm is a GSP-certified company focused on providing logistics services to, and distributing and marketing prescription drugs manufactured

by, third-party pharmaceutical companies in China. Hutchison Sinopharm also distributes certain products from Hutchison Healthcare's Zhi Ling Tong infant nutrition brand. Hutchison Sinopharm also continues to operate its legacy business which was primarily focused on providing logistics and distribution services, primarily within Shanghai, to third-party pharmaceutical companies.

We intend to increasingly focus on expanding Hutchison Sinopharm to operate as a full-service, third-party prescription drug commercialization company in China. To this end, in 2015 Hutchison Sinopharm entered into agreements with multinational and Chinese pharmaceutical manufacturers seeking to market their products in China. Hutchison Sinopharm now has agreements to market and distribute two prescription products. The primary product is:

• Seroquel—in the second quarter of 2015, we became the exclusive first-tier distributor to distribute and market AstraZeneca's quetiapine tablets, under the Seroquel trademark in China. Seroquel is a first-line antipsychotic medicine for the treatment of schizophrenia and bipolar disorder, which was launched in China in 2001. Seroquel holds a 5.6% market share in China's approximately \$0.9 billion atypical anti-psychotic prescription drug market and 45% of China's generic quetiapine market, primarily as a result of being the first-mover and original patent holder on quetiapine. Seroquel is the only brand in China to have an extended release formulation, which in 2017 was included on China's National Drug reimbursement List, thereby providing us with major competitive advantage over quetiapine generics.

Hutchison Sinopharm is the exclusive marketing agent for Seroquel tablets in China. As of December 31, 2017, Shanghai Hutchison Pharmaceuticals had a dedicated medical sales team of about 120 people to support Hutchison Sinopharm's commercialization of Seroquel. The new China two-invoice system, explained in more detail below, came into effect in October 2017, at which point the Seroquel operating model began progressively switching to a fee-for-service model.

Subject to Hutchison Sinopharm's continued delivery of pre-specified annual sales targets, which would require approximately 22% sales growth in 2018 and 15% per year thereafter, we can continue to retain exclusive commercial rights to Seroquel in China until 2025.

In the first quarter of 2015, we began to exclusively co-promote Merck Serono's bisoprolol fumarate tablets, under the Concor trademark, in a few provinces in China. Concor is the number two beta-blocker in China with an approximately 18% national market share in China's beta-blocker drug market and 70% of China's generic bisoprolol market. Hutchison Sinopharm was the exclusive marketing agent in six provinces, markets that contain over 360 million people. Hutchison Sinopharm created synergy with Shanghai Hutchison Pharmaceuticals's existing cardiovascular medical sales team who now details Concor alongside its She Xiang Bao Xin pills on a fee-for-service basis.

China has begun implementing a new regulatory two-invoice system on a province-by-province basis. In principle, the purpose of the two-invoice system is to restrict the number of layers in the drug distribution system in China, in order to improve transparency, compliant business conduct and efficiency. The impact to us is that, starting in October 2017, the Seroquel sales model, in which our consolidated revenues historically reflected total gross sales of Seroquel, began to shift to a fee-for-service model similar to that used all along on Concor. This change will reduce the top-line revenues that Hutchison Sinopharm will in the future be able to record from sales of Seroquel as well as many of our other third-party customers. Importantly however, this drop in reported sales will have no material impact on profitability, the service fees paid to Hutchison Sinopharm, and will have limited impact to our commercial team operations and expansion plans.

#### Consumer Health Business

Our Consumer Health business is a profitable business, focusing primarily on the manufacture, marketing and distribution of over-the-counter pharmaceutical products and other natural and organic consumer products in China. Our Consumer Health products business includes:

- Hutchison Baiyunshan, a joint venture established in 2005 which focuses primarily on the manufacture, marketing and distribution of proprietary over-the-counter pharmaceutical products.
   50% of this joint venture is owned by us and 50% by Guangzhou Baiyunshan, a leading China-based pharmaceutical company listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange,
- Hutchison Hain Organic, a joint venture which was established in 2009 and has rights to market and distribute a broad range of natural and organic consumer products under brands owned by Hain Celestial in nine Asian territories,
- Hutchison Healthcare, a wholly owned subsidiary which was established in 2001 and manufactures
  and sells health supplements and licenses its infant nutrition products to Hutchison Sinopharm for
  distribution, and
- Hutchison Consumer Products, a wholly owned subsidiary which was established in 2007 that distributes and markets certain third-party health-related consumer products.

**Hutchison Baiyunshan**—manufacturing, marketing and distributing proprietary over-the-counter pharmaceutical products

Hutchison Baiyunshan primarily engages in the manufacture, marketing and distribution of proprietary over-the-counter pharmaceutical products. Its "Bai Yun Shan" brand is a market-leading household-name, established over 40 years ago and is known by the majority of Chinese consumers. As of December 31, 2017, Hutchison Baiyunshan held 189 registered drug licenses in China, of which 82 are included in the National Medicines Catalogue. In addition, 31 of Hutchison Baiyunshan's products, of which 12 are in active production, are represented on China's National Essential Medicines List. As of the end of 2017, substantially all pharmaceutical products manufactured and sold by Hutchison Baiyunshan in 2017 were capable of being reimbursed under the National Medicines Catalogue.

Hutchison Baiyunshan's key products are two generic over-the-counter therapies which are each listed on the LPDL:

- Fu Fang Dan Shen tablets—generic over-the-counter drugs for the treatment of chest congestion and angina pectoris to promote blood circulation and relieve pain, which represented approximately 26% of the sales of Hutchison Baiyunshan in 2017; and
- Banlangen granules—for the treatment of viral flu, fever, and respiratory tract infections which represented approximately 26% of the sales of Hutchison Baiyunshan in 2017.

Hutchison Baiyunshan's products are manufactured in-house at its GMP-certified facilities in Guangzhou, Guangdong province and Bozhou, Anhui province. A portion of Hutchison Baiyunshan's products had historically been manufactured by third-party contract manufacturers until its new higher capacity facility in Bozhou became operational in August 2017. Hutchison Baiyunshan is also in the process of negotiating the return of its land use rights for the approximately 30,000 square meter unused plot of land in Guangzhou, which has been listed for sale as part of the Guangzhou municipal government's urban redevelopment scheme plan since 2016.

Hutchison Baiyunshan also operates two Chinese good agriculture practice, or GAP, certified cultivation sites through its subsidiaries for growing the herbs used in its over-the-counter products in Heilongjiang and Henan provinces in China. In addition, Hutchison Baiyunshan generates revenue by

supplying raw materials produced by its cultivation operations to its collaboration partner, Guangzhou Pharmaceuticals.

Hutchison Baiyunshan sells its products directly to regional distributors across China who on-sell to local distributors, hospitals and clinics, pharmacies and other retailers, and employs its own sales representatives at a local level to market its products and promote over-the-counter sales to retailers.

In September 2017, Hutchison Baiyunshan divested its 60% shareholding in Nanyang Baiyunshan Hutchison Whampoa Guanbao Pharmaceutical Company Limited, or Guanbao, for consideration approximately equal to its carrying value. Guanbao was a GSP distribution company which had been established via a joint venture in 2012. It was a low margin, primarily third-party over-the-counter logistics business, with operations limited mainly to Henan province, and had proven to be a business with no strategic value to our company.

As of December 31, 2017, Hutchison Baiyunshan had approximately 1,000 sales representatives and over 1,000 manufacturing employees across China.

**Hutchison Hain Organic**—marketing and distributing Hain Celestial-licensed natural and organic food and personal care products

Hutchison Hain Organic is a joint venture with Hain Celestial, a Nasdaq-listed, natural and organic food and personal care products company. Hutchison Hain Organic distributes a broad range of over 500 imported organic and natural products.

Pursuant to its joint venture agreement, Hutchison Hain Organic has rights to market and distribute Hain Celestial's products within nine Asian territories. We believe the key strategic product for Hutchison Hain Organic is Earth's Best organic infant formula, a leading brand in the United States, which Hutchison Hain Organic began to sell in China in mid-2015. Earth's Best organic infant formula is imported from U.S. manufacturer Perrigo Company and is sold in China through an online retailer and specialty retail outlets. Hutchison Hain Organic's other products are distributed to hypermarkets, specialty stores and other retail outlets in Hong Kong, China and across seven other territories in Asia mainly through third-party local distributors, including retail chains owned by affiliates of CK Hutchison.

## **Hutchison Healthcare**—manufacturing, marketing and distributing health supplements

Hutchison Healthcare is our wholly owned subsidiary and is primarily engaged in the manufacture and sale of health supplements. Hutchison Healthcare's major product is Zhi Ling Tong DHA capsules, a health supplement, made from algae DHA oil, for the promotion of brain and retinal development in babies and young children, which is distributed by Hutchison Sinopharm.

The majority of Hutchison Healthcare's products are contract manufactured at a dedicated GMP-certified manufacturing facility operated by a third party and distributed to hospital pharmacies, specialty stores and drugstore chains.

## Hutchison Consumer Products—distribution of consumer products

Hutchison Consumer Products is our wholly owned subsidiary that is primarily engaged in the distribution of third-party consumer products in Asia.

### Competition

# **Innovation Platform Competition**

The biotechnology and pharmaceutical industries are highly competitive. While we believe that our highly selective drug candidates, experienced development team and chemistry-focused scientific approach provide us with competitive advantages, we face potential competition from many different sources,

including major pharmaceutical, specialty pharmaceutical and biotechnology companies. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and/or new drugs that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology and other related markets that address inhibition of kinases in cancer and immunological diseases. There are other companies working to develop targeted therapies in the field of kinase inhibition for cancer and immunological diseases. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We also compete with pharmaceutical and biotechnology companies that develop and market monoclonal antibodies as targeted therapies for the treatment of cancer and immunological diseases.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our drug candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our drug candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Below is a summary of existing therapies and therapies currently under development that may become available in the future which may compete with each of our eight clinical-stage drug candidates.

### Savolitinib

While there are currently no approved selective c-Met inhibitors on the market, there are several c-Met inhibitors currently undergoing clinical trials for the treatment of renal cell carcinoma, non-small cell lung cancer and gastric cancer such as Cabometyx (cabozantinib) (VEGFR/c-Met/Ret inhibitor approved for renal cell carcinoma and in development for non-small cell lung cancer), tepotinib (c-Met inhibitor in development for non-small cell lung cancer), glesatinib (c-Met and Axl tyrosine kinase inhibitor in development for non-small cell lung cancer), emibetuzumab (MET inhibitor in development for non-small cell lung cancer) and AMG 337 (c-Met kinase inhibitor in development for stomach cancer). Xalkori (ALK, ROS1 and c-Met inhibitor marketed for non-small cell lung cancer) is a multi-kinase inhibitor that less selectively inhibits c-Met. Merestinib (MST1R, FLT3, AXL, MERTK, TEK, ROS1, DDR1/2, MKNK1/2 and c-Met inhibitor in development for non-small cell lung cancer) is also a multi-kinase inhibitor.

## Fruquintinib

Approved VEGF inhibitors on the market for the treatment of colorectal cancer include Avastin (anti-VEGF monoclonal antibody), Cyramza (anti-VEGFR2 monoclonal antibody), Stivarga (VEGFR/TIE2 inhibitor) and Zaltrap (ziv-aflibercept) (VEGF inhibitor). Cyramza is approved for the treatment of non-small cell lung cancer and gastric cancer, and Avastin is also approved for non-small cell lung cancer. In addition, Inlyta and Caprelsa (vandetanib) use a similar mechanism of action as the VEGF inhibitors on the market and are currently being studied for the treatment of colorectal cancer. Other VEGFR inhibitors being developed for the treatment of non-small cell lung cancer include anlotinib, apatinib, Cabometyx, Lenvima (lenvatinib), lucitanib and Caprelsa. VEGFR inhibitors being developed for the treatment of gastric cancer include dovitinib, telatinib and regorafenib. In China, apatinib has been approved for the treatment of third-line gastric cancer and anlotinib has an NDA under review for the treatment of third-line non-small cell lung cancer.

## Sulfatinib

Sutent (VEGFR inhibitor) and Afinitor (mTOR inhibitor) have been approved for the treatment of pancreatic neuroendocrine tumors. Somatuline Depot (Lanreotide) is a growth hormone release inhibitor that has been approved for the treatment of gastroenteropancreatic neuroendocrine tumors. Sandostatin (octreotide) is a growth hormone and insulin-like growth factor-1 inhibitor that has also been approved for neuroendocrine tumors. Lutathera (Lu-dotatate), a somatostatin receptor targeting radiotherapy, recently received NDA approval from the FDA for the treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors. Furthermore, both small molecules and monoclonal antibodies are being developed for the treatment of neuroendocrine tumors. Compounds undergoing development for neuroendocrine tumors include Vargatef (nintedanib, a tyrosine kinase inhibitor), milciclib (tyrosine kinase inhibitor) and Zybrestat (fosbretabulin, a microtubule/tubulin inhibitor being studied for thyroid cancer). Cometriq (an additional brand name for cabozantinib) has been marketed for thyroid cancer and is being studied for neuroendocrine tumors. In addition, Avastin is an anti-VEGF monoclonal antibody being studied for neuroendocrine tumors.

# **Epitinib**

Although no EGFR tyrosine kinase inhibitors have been specifically approved for non-small cell lung cancer with brain metastasis or primary brain tumor, many have been approved for the treatment of non-small cell lung cancer with EGFR activating mutations, including Gilotrif (EGFR/HER2 inhibitor), Iressa, Tarceva, Conmana and Tagrisso. Moreover, Tagrisso, tesevatinib (EGFR/HER2/VEGFR inhibitor) and AZD3759 (EGFR inhibitor) are in development for the treatment of non-small cell lung cancer with brain metastasis while Alecensa (alectinib, an ALK inhibitor) has already been approved.

# **Theliatinib**

Approved EGFR inhibitors on the market include Iressa and Tarceva, although these drugs reach insufficient drug concentrations to suppress wild-type EGFR effectively. In addition, monoclonal antibodies, such as Erbitux, which are approved for the treatment of certain EGFR over-expression tumor types, are less effective for EGFR gene amplified patients. Other small molecule therapies currently being studied for the treatment of esophageal tumors include Gilotrif and Conmana.

### **HMPL-523**

There has been extensive research on oral small-molecule Syk inhibitors due to the major unmet medical need in inflammation and oncology. No small molecule drug candidates targeting Syk specifically have been approved to date due to the severe off-target toxicity as a result of poor kinase selectivity and possibly poor pharmacokinetic properties. GS-9876 is a Syk inhibitor currently in clinical studies for rheumatoid arthritis. Syk inhibitors currently in clinical studies for hematological cancers include entospletinib, cerdulatinib and TAK-659. In addition, Janus tyrosine kinase, or JAK, inhibitors such as Xeljanz (tofacitinib JAK-3 inhibitor, marketed for rheumatoid arthritis and in development for ulcerative colitis, Crohn's disease and myelofibrosis), Jakafi (ruxolitinib, JAK-1/2 inhibitor, marketed for myelofibrosis and in development for acute myelogenous leukemia), baricitinib (JAK-1/2 inhibitor in development for rheumatoid arthritis) and filgotinib (JAK-1 inhibitor in development for rheumatoid arthritis) and TNFα inhibitors marketed for rheumatoid arthritis, such as Enbrel, Remicade, Humira and Cimzia, are also expected to be potential competitors of HMPL-523 if it is approved.

However, most anti-TNF $\alpha$  monoclonal antibodies are applicable for severe disease only as these injectables significantly suppress the entire immune system for a substantial period of time.

### **HMPL-689**

Zydelig is a PI3Kδ inhibitor that has been approved for the treatment of refractory/relapsed follicular lymphoma, small lymphocytic lymphoma as a monotherapy and chronic lymphatic leukemia in combination with Rituxan. In addition, several drug candidates that inhibit PI3Kδ are in clinical development, including duvelisib, copanlisib, gedatolisib, INCB040093, GS-9901, umbralisib and AMG 319.

## **HMPL-453**

To date, there are no approved therapies that specifically target the FGFR signaling pathway. Several small molecule FGFR tyrosine kinase inhibitors are in early clinical trials for solid tumors, including AZD4547, infigratinib, rogaratinib, BLU-554, erdafitinib, TAS-120, Debio 1347, INCB054828, and LY3076226. Similarly, FGFR specific monoclonal antibodies in development include MFGR1877S and B-701.

### HM004-6599

The current standard of care for inflammatory bowel disease starts with mesalazine, while for the non-responding patients, various forms of corticosteroids and immunosuppressant drugs and anti-tumor necrosis factor agents are prescribed. Several anti-TNF $\alpha$  monoclonal antibody injectables, such as Cimzia, Humira, Remicade and Simponi (golimumab) (abandoned in Phase I for Crohn's disease), have been approved for the treatment of ulcerative colitis and Crohn's disease. However, most anti-TNF $\alpha$  monoclonal antibodies are applicable for severe disease only as these injectables significantly suppress the entire immune system for a substantial period of time.

# **Commercial Platform Competition**

Our Commercial Platform's Prescription Drugs business competes in the pharmaceutical industry in China, which is highly competitive and is characterized by a number of established, large pharmaceutical companies, as well as some smaller emerging pharmaceutical companies. Our Prescription Drugs business faces competition from other pharmaceutical companies in China engaged in the development, production, marketing or sales of prescription drugs, in particular cardiovascular drugs. The barrier of entry for the PRC pharmaceutical industry primarily relates to regulatory requirements in connection with the production of pharmaceutical products and new product launches.

The identities of the key competitors with respect to our Prescription Drugs business vary by product, and, in certain cases, different competitors that have greater financial resources than us may elect to focus these resources on developing, importing or in-licensing and marketing products in the PRC that are substitutes for our products and may have broader sales and marketing infrastructure with which to do so.

We believe that we compete primarily on the basis of brand recognition, pricing, sales network, promotion activities, product efficacy, safety and reliability. We believe our continued success will depend on our Prescription Drugs business's capability to: maintain profitability of its core product, She Xiang Bao Xin pills, successfully market and distribute in-licensed products such as Seroquel and Concor, obtain and maintain regulatory approvals, develop drug candidates with market potential, maintain an efficient operational model, apply technologies to production lines, attract and retain talented personnel, maintain high quality standards, and effectively market and promote the products sold by our Prescription Drugs business. Key competitors for She Xiang Bao Xin pills include Tasly Holding (Compound Danshen Dropping Pill) and Shijiazhuang Yiling Pharmaceutical (Tong Xin Luo Capsule). In addition, Hunan Dongting Pharma and Suzhou First Pharma are key competitors to our Prescription Drugs business in licensed drug Seroquel.

Our Commercial Platform's Consumer Health business competes in a highly fragmented market in Asia, particularly in our primary market in China. We believe that our Consumer Health business competes primarily on the basis of brand recognition, pricing, sales network, promotion activities, product safety and reliability. We believe our continued success will depend on our Consumer Health business's capability to: maintain profitability of its core products, Fu Fang Dan Shen tablets and Banlangen granules, differentiate its products vis-a-vis those of competitors, successfully market and distribute in-licensed products such as Earth's Best infant formula, maintain an efficient operational model, attract and retain talented personnel, maintain high quality standards, and effectively market and promote the products sold by our Consumer Health business. In China, Fu Fang Dan Shen tablets and Banlangen granules are generic over-the-counter drugs marketed by several manufacturers. Key competitors include Shanghai LeiYunShang Pharmaceutical, Yunnan Baiyao and Beijing Tongrentang in the Fu Fang Dan Shen market, and include Beijing Tongrentang and Guangzhou Xiangxue Pharmaceutical for the Banlangen market.

# Patents and Other Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our Innovation Platform's drug candidates, our Commercial Platform's products and other know-how. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in various jurisdictions related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

## Patents

We and our joint ventures file patent applications directed to our Innovation Platform's drug candidates and our Commercial Platform's products in an effort to establish intellectual property positions with regard to new small molecule compounds and/or extracts of natural herbs, their compositions as well as their medical uses in the treatment of diseases. In relation to our Innovation Platform, we also file patent applications directed to crystalline forms, formulations, processes, key intermediates, and secondary uses as clinical trials for our drug candidates evolve. We file such patent applications in major market jurisdictions, including the United States, Europe, Japan and China as well as Argentina, Australia, Brazil, Canada, Chile, Indonesia, Israel, India, South Korea, Mexico, Malaysia, New Zealand, Peru, Philippines, Singapore, Ukraine and South Africa. We do not currently in-license any patents except to the extent necessary to ensure our drug candidate fruquintinib has freedom to operate as discussed below.

## Our Innovation Platform Patents

As of December 31, 2017, we had 151 issued patents, including 18 Chinese patents, 19 U.S. patents and eight European patents, 146 patent applications pending in the above major market jurisdictions, and two pending Patent Cooperation Treaty, or PCT, patent applications relating to the drug candidates of our Innovation Platform. As of the same date, our joint venture Nutrition Science Partners had 24 issued patents and three pending patent applications relating to HMPL-004 and its reformulation HM004-6599. The intellectual property portfolios for our most advanced drug candidates are summarized below. Some of these portfolios, such as HMPL-453 and HMPL-689, are in very early stages of development. With respect to most of the pending patent applications covering our drug candidates, prosecution has yet to commence. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office is often significantly narrowed by the time when they issue, if they issue at all. We expect this to be the case for our pending patent applications referred to below.

**Savolitinib**—The intellectual property portfolio for savolitinib contains issued patents and patent applications directed to novel small molecule compounds as well as methods of treating cancers with such compounds. As of December 31, 2017, we owned 20 patents in this family, including patents in the United

States, Europe and Japan, and we had 30 patent applications pending in various other jurisdictions, including China. Our European patent is also registered in Hong Kong. Our issued patents will expire in 2030. Our collaboration partner AstraZeneca is responsible for maintaining and enforcing the intellectual property portfolio for savolitinib.

Fruquintinib—The intellectual property portfolio for fruquintinib contains three patent families.

The first patent family for fruquintinib is directed to novel small molecule compounds as well as methods of treating tumor angiogenesis-related disorders with such compounds. As of December 31, 2017, we owned three U.S. patents, one Chinese patent and one Taiwanese patent in this family, each of which will expire in 2028. We also owned patents in Europe and 13 other jurisdictions expiring in 2029 and had two patent applications pending in Japan.

The second patent family is directed to crystalline forms of fruquintinib as well as methods of treating tumor angiogenesis-related disorders with such forms. As of December 31, 2017, we had one patent application pending in China in this family, which, if issued, would have an expiration date in 2034. We have also filed PCT and Taiwanese patent applications for this family which, if issued, will each have expiration dates in 2035.

The third patent family is directed to the method of preparing one of the critical intermediates used in the manufacturing process of fruquintinib. With respect to this patent family, we have a patent application pending in China, which, if issued, will have an expiration date in 2034.

We also in-license certain freedom-to-operate rights from AstraZeneca, which grant us non-exclusive rights within China and Hong Kong to develop and commercialize pharmaceutical compounds used in fruquintinib which are covered by one of its patents.

Sulfatinib—The intellectual property portfolio for sulfatinib contains four patent families.

The first patent family for sulfatinib is directed to novel small molecule compounds as well as methods of treating tumor angiogenesis-related disorders with such compounds. As of December 31, 2017, in this patent family we owned one Chinese patent expiring in 2027 and 12 patents in various other jurisdictions, including the United States expiring in 2031, and Europe and Japan, each expiring in 2028. As of December 31, 2017, we also had one patent application pending in Brazil.

The second patent family is directed to the crystalline forms of sulfatinib as well as methods of treating tumor angiogenesis-related disorders with such forms. As of December 31, 2017, in this patent family we owned two patents in China expiring in 2029 and 2030, respectively, and we owned 14 patents in other countries, including the United States which will expire in 2031 and Europe which will expire in 2030. As of December 31, 2017, we also had two patent applications pending in other jurisdictions.

The third patent family is directed to the formulation of a micronized active pharmaceutical ingredient used in sulfatinib as well as methods of treating tumor angiogenesis-related disorders with such formulation. With respect to this patent family, we have 17 patent applications pending in various jurisdictions, including China, the U.S. and Europe.

The fourth patent family was filed in 2016 and is subject to confidential review by the patent authorities.

**HMPL-523 Syk Inhibitor**—The intellectual property portfolio for HMPL-523 contains two patent families.

The first patent family is directed to novel small molecule compounds as well as methods of treating cancers, inflammatory diseases, allergic diseases, cell-proliferative diseases, and autoimmune diseases with such compounds. As of December 31, 2017, we owned 16 patents in this family in various jurisdictions, including the United States, China and South Korea, each of which will expire in 2032. As of December 31,

2017, we also had nine patent applications in this family pending in jurisdictions including the United States.

The second patent family was filed in 2017 and is subject to confidential review by the patent authorities.

Epitinib—The intellectual property portfolio for epitinib contains three patent families.

The first patent family is directed to novel small molecule compounds as well as methods of treating cancers with such compounds. As of December 31, 2017, we owned patents in China and Taiwan expiring in 2028, a patent in the United States expiring in 2031 and patents in 12 other jurisdictions, including Europe, each expiring in 2029. As of December 31, 2017, we also had two patent applications in this family pending in other jurisdictions.

The second and third patent families were filed in 2017 and are subject to confidential review by the patent authorities.

Theliatinib—The intellectual property portfolio for theliatinib contains two patent families.

The first patent family is directed to novel small molecule compounds as well as methods of treating cancers with such compounds. As of December 31, 2017, we owned 15 patents in this family in various jurisdictions, including China and Japan, each of which will expire in 2031. As of December 31, 2017, we also had four patent applications in this family pending in various jurisdictions. Our Chinese patent was also registered in Hong Kong and Macau.

The second patent family was filed in 2017 and is subject to confidential review by the patent authorities.

HMPL-689—The intellectual property portfolio for HMPL-689 contains patent applications directed to novel small molecule compounds as well as uses of such compounds. As of December 31, 2017, we had filed 24 patent applications pending in various jurisdictions, including Argentinean, Chinese, and Taiwanese and PCT applications, which, if issued, will each have expiration dates in 2035.

**HMPL-004/HM004-6599**—The intellectual property portfolio for HMPL-004/HM004-6599 is composed of four patent families.

The first patent family is directed to methods of treating inflammatory bowel disease with the compounds related to andrographolides, which are a type of organic plant extract used in drug formulation. As of December 31, 2017, we had one U.S. patent in this family with an expiration date in 2026.

The second patent family is directed to certain andrographolides as well as the method of treating inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis, with such andrographolides. As of December 31, 2017, with respect to this family, we had one Chinese patent and 12 patents in various other jurisdictions, including the United States, Europe and Japan. Our Chinese patent expires in 2024, and each of our other issued patents expires in 2025.

The third patent family is directed to certain andrographolides, a solid dosage form comprising certain andrographolides, as well as the method of treating inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis, with such andrographolides. As of December 31, 2017, we owned one Chinese patent expiring in 2027, two U.S. patents expiring in 2027 and 2029, respectively, and seven patents in various other jurisdictions, each expiring in 2028.

The fourth patent family was filed in 2016 and is subject to confidential review by the patent authorities.

We had also taken steps to seek patent protection for a sustainable release formulation of andrographolides, but that was abandoned as of December 31, 2017.

HMPL-453—The intellectual property portfolio for HMPL-453 contains patent applications directed to novel small molecule compounds as well as methods of treating cancers with the compounds. As of December 31, 2017, we owned 6 patents in this family in various jurisdictions, including Japan and the United States, each of which will expire in 2034. As of December 31, 2017, we had 18 patent applications pending in various jurisdictions, including China.

Our Commercial Platform Patents

## **Prescription Drugs Patents**

As of December 31, 2017, our Prescription Drugs joint venture Shanghai Hutchison Pharmaceuticals had 43 issued patents and ten pending patent applications in China, including patents for its key prescription products described below.

She Xiang Bao Xin Pills. As of December 31, 2017, Shanghai Hutchison Pharmaceuticals held an invention patent in China directed to the formulation of the She Xiang Bao Xin pill. Under PRC law, invention patents are granted for new technical innovations with respect to products or processes. Invention patents in China have a maximum term of 20 years. This patent will expire in 2029. The "Confidential State Secret Technology" status protection on the She Xiang Bao Xin pill technology held by Shanghai Hutchison Pharmaceuticals, as certified by China's Ministry of Science and Technology and State Secrecy Bureau, expired recently, and as of December 31, 2017, Shanghai Hutchison Pharmaceuticals was in the process of renewing such protection status.

Danning Tablets. As of December 31, 2017, Shanghai Hutchison Pharmaceuticals also held an invention patent in China directed to the formulation of the Danning tablet. This patent will expire in 2027.

### **Consumer Health Patents**

Many of the products sold by our Consumer Health Products joint venture Hutchison Baiyunshan, including its Banlangen granules and Fu Fang Dan Shen tablets, are generic, over-the-counter products for which Hutchison Baiyunshan does not hold patents. As of December 31, 2017, Hutchison Baiyunshan had 74 issued patents in China and one in each of Australia and Singapore.

## Patent Term

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions, a patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. In the future, if and when our drug candidates receive approval by the FDA or other regulatory authorities, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each drug and other factors. There can be no assurance that any of our pending patent applications will be issued or that we will benefit from any patent term extension.

As with other pharmaceutical companies, our or our joint ventures' ability to maintain and solidify our proprietary and intellectual property position for our drug candidates or our or their Commercial Platform products and technologies will depend on our or our joint ventures' success in obtaining effective patent

claims and enforcing those claims if granted. However, our or our joint ventures' pending patent applications and any patent applications that we or they may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our or our joint ventures' patents. Any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority of filing covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States, China or other markets that also claim technology or therapeutics to which we or our joint ventures have rights, we or our joint ventures may have to participate in interference proceedings, which could result in substantial costs to us, even if the eventual outcome is favorable to us, which is highly unpredictable. In addition, because of the extensive time required for clinical development and regulatory review of a drug candidate we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting protection such patent would afford the respective product and any competitive advantage such patent may provide.

### **Trade Secrets**

In addition to patents, we and our joint ventures rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our or their competitive position. We and our joint ventures seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality, and invention assignment agreements with our employees and consultants. We and our joint ventures have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we and our joint ventures enter into are designed to protect our or our joint ventures' proprietary information and the agreements or clauses requiring assignment of inventions to us or our joint ventures, as applicable, are designed to grant us or our joint ventures, as applicable, ownership of technologies that are developed through our or their relationship with the respective counterpart. We cannot guarantee, however, that these agreements will afford us or our joint ventures adequate protection of our or their intellectual property and proprietary information rights.

## Trademarks and Domain Names

We conduct our business using trademarks with various forms of the "Hutchison," "Chi-Med" and "China-MediTech" brands, as well as domain names incorporating some or all of these trademarks. In April 2006, we entered into a brand license agreement with Hutchison Whampoa Enterprises Limited, an indirect wholly owned subsidiary of CK Hutchison, pursuant to which we have been granted a non-exclusive, non-transferrable, royalty-free right to use such trademarks, domain names and other intellectual property rights owned by the CK Hutchison group in connection with the operation of our business worldwide. See Item 7.B. "Related Party Transactions—Relationship with CK Hutchison—Intellectual property licensed by the CK Hutchison group" for more details.

In addition, our joint ventures seek trademark protection in China for their Commercial Platform products. As of December 31, 2017, our joint ventures Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan owned a total of 183 trademarks in the aggregate related to products sold by them. For example, the name "Shang Yao" is a registered trademark of Shanghai Hutchison Pharmaceuticals in China for certain uses including pharmaceutical preparations. In addition, our joint venture Hutchison Baiyunshan has been granted a royal-free license to use the registered trademark "Bai Yun Shan" for a term equal to its operational period of the joint venture by Guangzhou Baiyunshan.

# **Raw Materials and Supplies**

Raw materials and supplies are ordered based on our or our joint ventures' respective sales plans and reasonable order forecasts and are generally available from our or our joint ventures' own cultivation operations and various third-party suppliers in quantities adequate to meet our needs. While we do experience price fluctuations associated with our raw materials, we have not experienced any material disruptions in the supply of these raw materials in the past. See Item 3.D. "Risk Factors—Our Commercial Platform's principal products involve the cultivation or sourcing of key raw materials including botanical products, and any supply failure or price fluctuations could adversely affect our Commercial Platform's ability to manufacture our products."

If any one of these supply arrangements or agreements were to be terminated or the ability of any one of these suppliers to perform under the applicable agreements were to be materially and adversely affected, we believe that we will be able to locate, qualify and enter into an agreement with a new supplier on a timely basis. We expect that our and our joint ventures' existing manufacturing facilities, and outside sources will allow us to meet near-term manufacturing needs for our commercial products and other drug candidate products that are in clinical trials.

### **Quality Control and Assurance**

We have our own independent quality control system and devote significant attention to quality control for the designing, manufacturing and testing of our products. We have established a strict quality control system in accordance with CFDA regulations. Our laboratories fully comply with the Chinese GMP guidelines and are staffed with highly educated and skilled technicians to ensure quality of all batches of product release. We monitor in real time our operations throughout the entire production process, from inspection of raw and auxiliary materials, manufacture, delivery of finished products, clinical testing at hospitals, to ethical sales tactics. Our quality assurance team is also responsible for ensuring that we are in compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies and managing internal and external quality performance of our company and our joint ventures, Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan.

### **Certificates and Permits**

Hutchison MediPharma (Suzhou) Limited holds a pharmaceutical manufacturing license issued by its local regulatory authority expiring on December 31, 2020.

Hutchison Sinopharm holds a GSP certificate issued by its local regulatory authority expiring on October 22, 2019. It also holds a pharmaceutical trading license issued by its local regulatory authority expiring on August 24, 2019.

Shanghai Hutchison Pharmaceuticals holds a pharmaceutical manufacturing license from its local regulatory authorities expiring on December 31, 2020. Shanghai Hutchison Pharmaceuticals also holds three GMP certificates issued by its local regulatory authority and the CFDA. The three GMP certificates will expire on November 16, 2021, August 14, 2021 and December 3, 2022, respectively.

Shanghai Shangyao Hutchison Whampoa GSP Company Limited, a subsidiary of Shanghai Hutchison Pharmaceuticals, holds a pharmaceutical trading license from its local regulatory authority expiring on December 29, 2019. It also holds a GSP certificate issued by its local regulatory authority expiring on April 21, 2020.

Hutchison Baiyunshan holds a pharmaceutical manufacturing license issued by its local regulatory authority expiring on December 31, 2020. Hutchison Baiyunshan holds three GMP certificates issued by its local regulatory authority expiring on December 10, 2018, December 21, 2020 and March 18, 2020, respectively.

Hutchison Whampoa Guangzhou Baiyunshan Pharmaceuticals Limited, a subsidiary of Hutchison Baiyunshan, holds a GSP certificate issued by its local regulatory authority expiring on January 15, 2020. It also holds a pharmaceutical trading license issued by its local regulatory authority expiring on November 12, 2019.

Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine (Bozhou) Company Limited, a subsidiary of Hutchison Baiyunshan, holds a GMP certificate issued by its local regulatory authority expiring January 18, 2022. It also holds a pharmaceutical manufacturing license issued by its local regulatory authority expiring on December 31, 2020.

Hutchison Whampoa Baiyunshan Lai Da Pharmaceutical (Shan Tou) Company Limited, a subsidiary of Hutchison Baiyunshan, holds a GMP certificate issued by its local regulatory authority expiring February 28, 2021. It also holds a pharmaceutical manufacturing license issued by its local regulatory authority expiring December 31, 2020.

Nanyang Baiyunshan Hutchison Whampoa Guanbao Pharmaceutical Company Limited, which was divested by Hutchison Baiyunshan in September 2017, held a pharmaceutical trading license and a GSP certificate from its local regulatory authority.

## Regulation

This section sets forth a summary of the most significant rules and regulations affecting our business activities in China and the United States.

# Government Regulation of Pharmaceutical Product Development and Approval

# PRC Regulation of Pharmaceutical Product Development and Approval

Since China's entry to the World Trade Organization in 2001, the PRC government has made significant efforts to standardize regulations, develop its pharmaceutical regulatory system and strengthen intellectual property protection.

## Regulatory Authorities

In the PRC, the CFDA is the authority that monitors and supervises the administration of pharmaceutical products and medical appliances and equipment as well as food, health food and cosmetics. The CFDA's predecessor, the State Food and Drug Administration, or the SFDA, was established on August 19, 1998 as an organization under the State Council to assume the responsibilities previously handled by the Ministry of Health of the PRC, or the MOH, the State Pharmaceutical Administration Bureau of the PRC and the State Administration of Traditional Chinese Medicine of the PRC. The CFDA was founded in March 2003 to replace the SFDA.

The primary responsibilities of the CFDA include:

- monitoring and supervising the administration of pharmaceutical products, medical appliances and equipment as well as food, health food and cosmetics in the PRC;
- formulating administrative rules and policies concerning the supervision and administration of food, health food, cosmetics and the pharmaceutical industry; evaluating, registering and approving of new drugs, generic drugs, imported drugs and traditional Chinese medicine;
- approving and issuing permits for the manufacture and export/import of pharmaceutical products and medical appliances and equipment and approving the establishment of enterprises to be engaged in the manufacture and distribution of pharmaceutical products; and
- examining and evaluating the safety of food, health food and cosmetics and handling significant accidents involving these products.

The MOH is an authority at the ministerial level under the State Council and is primarily responsible for national public health. Following the establishment of the CFDA in 2003, the MOH was put in charge of the overall administration of the national health in the PRC excluding the pharmaceutical industry. In March 2008, the State Council placed the CFDA under the management and supervision of the MOH. The MOH performs a variety of tasks in relation to the health industry such as establishing social medical institutes and producing professional codes of ethics for public medical personnel. The MOH is also responsible for overseas affairs, such as dealings with overseas companies and governments. In 2013, the MOH and the National Population and Family Planning Commission were integrated into the National Health and Family Planning Commission of the PRC, or the NHFPC. The responsibilities of the NHFPC include organizing the formulation of national drug policies, the national essential medicine system and the National Essential Medicines List and drafting the administrative rules for the procurement, distribution and use of national essential medicines.

## Healthcare System Reform

The PRC government recently promulgated several healthcare reform policies and regulations to reform the healthcare system. On March 17, 2009, the Central Committee of the PRC Communist Party and the State Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System. On March 18, 2009, the State Council issued the Implementation Plan for the Recent Priorities of the Healthcare System Reform (2009-2011). On July 22, 2009, the General Office of the State Council issued the Five Main Tasks of Healthcare System Reform in 2009.

Highlights of these healthcare reform policies and regulations include the following:

- The overall objective of the reform is to establish a basic healthcare system to cover both urban and rural residents and provide the Chinese people with safe, effective, convenient and affordable healthcare services. The PRC government aims to extend basic medical insurance coverage to at least 90% of the country's population by 2011 and increase the amount of subsidies on basic medical insurance for urban residents and rural cooperative medical insurance to RMB120 per person per year by 2010. By 2020, a basic healthcare system covering both urban and rural residents should be established.
- The reforms aim to promote orderly market competition and improve the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population. From 2009, basic public healthcare services such as preventive healthcare, maternal and child healthcare and health education will be provided to urban and rural residents. In the meantime, the reforms also encourage innovations by pharmaceutical companies to eliminate low-quality and duplicative products.
- The five key tasks of the reform from 2009 to 2011 are as follows: (1) to accelerate the formation of a basic medical insurance system, (2) to establish a national essential drug system, (3) to establish a basic healthcare service system, (4) to promote equal access to basic public healthcare services, and (5) to promote the reform of public hospitals.

## Drug Administration Laws and Regulations

The PRC Drug Administration Law as promulgated by the Standing Committee of the National People's Congress in 1984 and the Implementing Measures of the PRC Drug Administration Law as promulgated by the MOH in 1989 have laid down the legal framework for the establishment of pharmaceutical manufacturing enterprises, pharmaceutical trading enterprises and for the administration of pharmaceutical products including the development and manufacturing of new drugs and medicinal preparations by medical institutions. The PRC Drug Administration Law also regulates the packaging, trademarks and the advertisements of pharmaceutical products in the PRC.

Certain revisions to the PRC Drug Administration Law took effect on December 1, 2001. They were formulated to strengthen the supervision and administration of pharmaceutical products, and to ensure the quality of pharmaceutical products and the safety of pharmaceutical products for human use. The revised PRC Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products. It regulates and prescribes a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies, and medicinal preparations of medical institutions and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products.

The PRC Drug Administration Law was later amended on December 28, 2013 and April 24, 2015 by the Standing Committee of the National People's Congress. It provides the basic legal framework for the administration of the production and sale of pharmaceutical products in China and covers the manufacturing, distributing, packaging, pricing and advertising of pharmaceutical products.

According to the PRC Drug Administration Law, no pharmaceutical products may be produced without a pharmaceutical production license. A manufacturer of pharmaceutical products must obtain a pharmaceutical production license from one of CFDA's provincial level branches in order to commence production of pharmaceuticals. Prior to granting such license, the relevant government authority will inspect the manufacturer's production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards.

The PRC Drug Administration Implementation Regulations promulgated by the State Council took effect on September 15, 2002 and were later amended on February 6, 2016 to provide detailed implementation regulations for the revised PRC Drug Administration Law.

# Examination and Approval of New Medicines

On July 10, 2007, the CFDA promulgated the Administrative Measures on the Registration of Pharmaceutical Products, or the Registration Measures, which became effective on October 1, 2007. Under the Registration Measures, new medicines generally refer to those medicines that have not yet been marketed in the PRC. In addition, certain marketed medicines may also be treated as new medicines if the type or application method of such medicines has been changed or new therapeutic functions have been added to such medicines. According to the Registration Measures, the approval of new medicines requires the following steps:

- upon completion of the pre-clinical research of the new medicine, application for registration of the new medicine will be submitted to the drug regulatory authorities at the provincial level for review in formalities. If all the formality requirements are met, the drug regulatory authorities at the provincial level will issue a notice of acceptance and conduct site inspections on the research and original data of the new medicine. The drug regulatory authorities at the provincial level will subsequently issue a preliminary opinion and notify a medical examination institute to conduct a sample examination on the new medicine (if the new medicine is a biological product);
- the drug regulatory authorities at the provincial level will then submit their preliminary opinion, inspection report and application materials to the Drug Review Center of the CFDA and notify the applicant of the progress;
- after receiving the application materials, the Drug Review Center of the CFDA will arrange for
  pharmaceutical, medical or other professionals to conduct a technical review on the application
  materials and request for supplemental materials and explanations, if necessary. After completion
  of the technical review, the Drug Review Center of the CFDA will issue an opinion and submit such
  opinion to the CFDA, along with the application materials;

- after receiving the technical opinion from the Drug Review Center, the CFDA will assess whether or not to grant the approval for conducting the clinical research on the new medicine;
- after obtaining the CFDA's approval for conducting the clinical research, the applicant may proceed with the relevant clinical research (which is generally conducted in three phases for a new medicine under the Registration Measures) at institutions with appropriate qualification:
  - Phase I refers to the preliminary clinical trial for clinical pharmacology and body safety. It is conducted to observe the human body tolerance for new medicine and pharmacokinetics, so as to provide a basis for determining the prescription plan.
  - Phase II refers to the stage of preliminary evaluation of clinical effectiveness. The purpose is to preliminarily evaluate the clinical effectiveness and safety of the medicine used on patients with targeted indication, as well as to provide a basis for determining the Phase III clinical trial research plan and the volume under the prescription plan.
  - Phase III is a clinical trial stage to verify the clinical effectiveness. The purpose is to test and determine the clinical effectiveness and safety of the medicine used on patients with targeted indication, to evaluate the benefits and risks thereof and, eventually, to provide sufficient basis for review of the medicine registration application.
  - Phase IV refers the stage of surveillance and research after the new medicines is launched. The purpose is to observe the clinical effectiveness and adverse effects of the medicine over a much larger patient population and longer time period than in Phase I to III clinical trials, and evaluate the benefits and risks when it is administered to general or special patient population in larger prescription volume.
- after completion of the relevant clinical research, the applicant shall submit its clinical research report together with the relevant supporting documents to the drug regulatory authorities at the provincial level and shall provide raw materials of the standard products and research result on relevant standard products to the PRC National Institute for the Control of Pharmaceutical and Biological Products;
- the drug regulatory authorities at the provincial level will then review the relevant documents in formalities. If all the formality requirements are met, the drug regulatory authorities at the provincial level will issue a notice of acceptance and within five days of notice and start conducting site inspections. The drug regulatory authorities at the provincial level will issue a preliminary opinion and then collect three samples of the new medicine (if the new medicine is not a biological product) and notify the relevant medicine examination institute to review the medicine standards;
- the drug regulatory authorities at the provincial level will then submit their preliminary opinion, inspection report and application materials to the Drug Review Center of the CFDA and notify the applicant of the progress;
- the medical examination institute will review the medicine standards and report its opinion to the Drug Review Center of the CFDA and send a copy of the opinion to the drug regulatory authorities at the provincial level and the applicant;
- after receiving the application materials, the Drug Review Center of the CFDA will arrange for pharmaceutical, medical or other professionals to conduct a technical review on the application materials and request for supplemental materials and explanations, if necessary. After completion of the technical review and if all the requirements are complied with, the Drug Review Center of the CFDA will report so to the Certification Center of the CFDA and notify the applicant that it may apply to the Certification Center of the CFDA for a site inspection;
- the applicant will apply to the Certification Center of the CFDA for a site inspection within six months after receiving the notice from the Drug Review Center of the CFDA;

- the Certification Center of the CFDA will arrange a site inspection on the process of manufacturing samples within thirty days after the application from the applicant to ensure the feasibility of the manufacturing process. The Certification Center of the CFDA will collect a sample (three samples if the new medicine is a biological product) for the medicine examination institute to examine. The Certification Center of the CFDA will prepare an inspection report within 10 days after the site inspection and submit the report to the Drug Review Center of the CFDA;
- the sample(s) shall be manufactured at a GMP-certified workshop. The medicine examination institute will examine the sample(s) under the reviewed medicine standards and prepare a report after completion the examination and submit the report to the Drug Review Center of the CFDA. A copy of the report will be available to the drug regulatory authorities at the provincial level and the applicant;
- the Drug Review Center of the CFDA will form a comprehensive opinion based on the technical opinion previously received, the report on site inspection and the result of sample examination and submit the comprehensive opinion and the application materials to the CFDA; and
- if all the regulatory requirements are satisfied, the CFDA will grant a new drug certificate and a pharmaceutical approval number (assuming the applicant has a valid Pharmaceutical Manufacturing Permit and the requisite production conditions for the new medicine have been met).

Any applicant who is not satisfied with the CFDA's decision to deny an application can appeal within 60 days of its receipt of the CFDA's decision. If the applicant is dissatisfied with the result of the appeal, it may apply for an administrative review with a special committee consisting of senior officials of the CFDA or file an administrative lawsuit with a people's court in China.

Pursuant to the Registration Measures, chemical drugs are categorized into six different registration classes. Class I New Chemical Drug is a new chemical drug that has never been marketed in China or abroad, including (1) crude drugs made by synthesis or semi-synthesis and the preparations thereof; (2) new effective monomer extracted from natural substances or by fermentation and the preparations thereof; (3) optical isomer obtained from existing drugs by chiral separation or synthesis and the preparations thereof; (4) drug with fewer components derived from marketed multi-component drugs; (5) new combination products; and (6) a preparation already marketed in China but with a newly added indication not yet approved in any country. Different application materials are required for each registration category.

In accordance with the Provisions on the Administration of Special Examination and Approval of Registration of New Drugs promulgated by the CFDA, issued and effective on January 7, 2009, an NDA that meets certain requirements as specified below will be handled with priority in the review and approval process, so-called "green-channel" approval. In addition, the applicant is entitled to provide additional materials during the review period besides those requested by the CFDA, and will have access to enhanced communication channels with the CFDA.

Applicants for the registration of the following new drugs are entitled to request priority treatment in review and approval: (i) active ingredients and their preparations extracted from plants, animals and minerals, and newly discovered medical materials and their preparations that have not been sold in the China market, (ii) chemical drugs and their preparations and biological products that have not been approved for sale at its origin country or abroad, (iii) new drugs with obvious clinical treatment advantages for such diseases as AIDS, therioma, and rare diseases, and (iv) new drugs for diseases that have not been treated effectively. Under category (i) or (ii) above, the applicant for drug registration may apply for special examination and approval when applying for the clinical trial of new drugs; under category (iii) or (iv) above, the applicant may only apply for special examination and approval when applying for manufacturing.

In addition, on December 21, 2017, the CFDA released the Opinions on Priority Review and Approval for Encouraging Drug Innovation, which further clarified that a fast track for drug registration will be available to:

- the following drugs with distinctive clinical value: (1) innovative drugs not sold within or outside China; (2) innovative drug transferred to be manufactured locally in China; (3) drugs using advanced technology, innovative treatment methods, or having distinctive treatment advantages; (4) traditional Chinese medicines (including ethnic medicines) with clear clinical position in treatment of serious diseases; and (5) new drugs listed in national major science and technology projects or national key research and development plans, and recognized by national clinical medicine research centers which conducted clinical trials of such drugs;
- drugs with distinctive clinical advantages for the prevention and treatment of the following diseases: HIV, phthisis, viral hepatitis, orphan diseases, malignant tumors, children's diseases, and characteristic and prevalent diseases in elders; and
- drugs which have been concurrently filed with the competent drug approval authorities in the United States or European Union for marketing authorization and passed such authorities' onsite inspections and are manufactured using the same production line in China.

It also specified that fast track status would be given to clinical trial applications for drugs with patent expiry within three years and manufacturing authorization applications for drugs with patent expiry within one year. Concurrent applications for new drug clinical trials which are already approved in the United States or European Union are also eligible for fast track CFDA approval.

# Drug Technology Transfer Regulations

On August 19, 2009, the CFDA promulgated the Administrative Regulations for Technology Transfer Registration of Drugs to standardize the registration process of drug technology transfer, which includes application for, and evaluation, examination, approval and monitoring of, drug technology transfer. Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer and the application for drug registration by the transferee according to the provisions in the new regulations. Drug technology transfer includes new drug technology transfer and drug production technology transfer.

# Conditions for the application for new drug technology transfer

Applications for new drug technology transfer may be submitted prior to the expiration date of the monitoring period of the new drugs with respect to:

- drugs with new drug certificates only; or
- drugs with new drug certificates and drug approval numbers.

For drugs with new drug certificates only and not yet in the monitoring period, or drug substances with new drug certificates, applications for new drug technology transfer should be submitted prior to the respective expiration date of the monitoring periods for each drug registration category set forth in the new regulations and after the issue date of the new drug certificates.

# Conditions for the application of drug production technology transfer

Applications for drug production technology transfer may be submitted if:

- the transferor holds new drug certificates or both new drug certificates and drug approval numbers, and the monitoring period has expired or there is no monitoring period;
- with respect to drugs without new drug certificates, both the transferor and the transferee are legally qualified drug manufacturing enterprises, one of which holds over 50% of the equity

interests in the other, or both of which are majority-owned subsidiaries of the same drug manufacturing enterprise;

• with respect to imported drugs with imported drug licenses, the original applicants for the imported drug registration may transfer these drugs to local drug manufacturing enterprises.

## Application for, and examination and approval of, drug technology transfer

Applications for drug technology transfer should be submitted to the provincial food and drug administration. If the transferor and the transferee are located in different provinces, the provincial food and drug administration where the transferor is located should provide examination opinions. The provincial food and drug administration where the transferee is located is responsible for examining application materials for technology transfer and organizing inspections on the production facilities of the transferee. Medical examination institutes are responsible for testing three batches of drug samples.

The Drug Review Center of the CFDA should further review the application materials, provide technical evaluation opinions and form a comprehensive evaluation opinion based on the site inspection reports and the testing results of the samples. The CFDA should determine whether to approve the application according to the comprehensive evaluation opinion of the Drug Review Center of the CFDA. An approval letter of supplementary application and a drug approval number will be issued to qualified applications. An approval letter of clinical trials will be issued when necessary. For rejected applications, a notification letter of the examination opinions will be issued with the reasons for rejection.

Permits and Licenses for Manufacturing and Registration of Drugs

## **Production Licenses**

To manufacture pharmaceutical products in the PRC, a pharmaceutical manufacturing enterprise must first obtain a Pharmaceutical Manufacturing Permit issued by the relevant pharmaceutical administrative authorities at the provincial level where the enterprise is located. Among other things, such a permit must set forth the permit number, the name, legal representative and registered address of the enterprise, the site and scope of production, issuing institution, date of issuance and effective period.

Each Pharmaceutical Manufacturing Permit issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. The enterprise is required to apply for renewal of such permit within six months prior to its expiry and will be subject to reassessment by the issuing authorities in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

### **Business Licenses**

In addition to a Pharmaceutical Manufacturing permit, the manufacturing enterprise must also obtain a business license from the administrative bureau of industry and commerce at the local level. The name, legal representative and registered address of the enterprise specified in the business license must be identical to that set forth in the Pharmaceutical Manufacturing Permit.

## **Registration of Pharmaceutical Products**

All pharmaceutical products that are produced in the PRC must bear a registered number issued by the CFDA, with the exception of Chinese herbs and Chinese herbal medicines in soluble form. The medicine manufacturing enterprises must obtain the medicine registration number before manufacturing any medicine.

### **GMP** Certificates

The World Health Organization encourages the adoption of GMP standards in pharmaceutical production in order to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final products.

The Guidelines on Good Manufacturing Practices, as amended in 1998 and 2010, or the Guidelines, took effect on August 1, 1999 and set the basic standards for the manufacture of pharmaceuticals. These Guidelines cover issues such as the production facilities, the qualification of the personnel at the management level, production plant and facilities, documentation, material packaging and labeling, inspection, production management, sales and return of products and customers' complaints. On October 23, 2003, the CFDA issued the Notice on the Overall Implementation and Supervision of Accreditation of Good Manufacturing Practice Certificates for Pharmaceuticals, which required all pharmaceutical manufacturers to apply for the GMP certificates by June 30, 2004. Those enterprises that failed to obtain the GMP certificates by December 31, 2004 would have their Pharmaceutical Manufacturing Permit revoked by the drug administrative authorities at the provincial level. On October 24, 2007, the CFDA issued Evaluation Standard on Good Manufacturing Practices which became effective on January 1, 2008. The GMP certificate is valid for a specific term and application for renewal must be submitted six months prior to its expiration date.

## Administrative Protection and Monitoring Periods for New Drugs

According to the Registration Measures, with a view to protecting public health, the CFDA may provide for administrative monitoring periods of up to five years for new drugs approved to be manufactured, to continually monitor the safety of those new drugs.

During the monitoring period of a new drug, the CFDA will not approve any other enterprise's application to manufacture, change the dosage of or import a similar new drug. The only exception is that the CFDA will continue to handle any application if, prior to the commencement of the monitoring period, the CFDA has already approved the applicant's clinical trial for a similar new drug. If such application conforms to the relevant provisions, the CFDA may approve such applicant to manufacture or import the similar new drug during the remainder of the monitoring period.

The Administrative Measures Governing the Production Quality of Pharmaceutical Products, or the Administrative Measures for Production, provides detailed guidelines on practices governing the production of pharmaceutical products. A GMP certification certifies that a manufacturer's factory has met certain criteria in the Administrative Measures for Production, which include: institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, maintenance of sales records and manner of handling customer complaints and adverse reaction reports.

According to the Administrative Measures for Certification of the Good Manufacturing Practices, effective on August 2, 2011, a manufacturer of pharmaceutical products shall reapply for a new GMP certification six months prior to its expiration date.

# Distribution of Pharmaceutical Products

According to the PRC Drug Administration Law and its implementing regulations and the Measures for the Supervision and Administration of Circulation of Pharmaceuticals, a manufacturer of pharmaceutical products in the PRC can only engage in the trading of the pharmaceutical products that the manufacturer has produced itself. In addition, such manufacturer can only sell its products to:

- wholesalers and distributors holding Pharmaceutical Distribution Permits;
- other holders of Pharmaceutical Manufacturing Permits; or

• medical practitioners holding Medical Practice Permits.

A pharmaceutical manufacturer in the PRC is prohibited from selling its products to end-users, or individuals or entities other than holders of Pharmaceutical Distribution Permits, the Pharmaceutical Manufacturing Permits or the Medical Practice Permits.

The granting of a Pharmaceutical Distribution Permit to wholesalers shall be subject to approval of the provincial level drug regulatory authorities, while the granting of a retailer permit shall be subject to the approval of the drug regulatory authorities above the county level. Unless otherwise expressly approved, no pharmaceutical wholesaler may engage in the retail of pharmaceutical products, and neither may pharmaceutical retailers engage in wholesale.

A pharmaceutical distributor shall satisfy the following requirements:

- personnel with pharmaceutical expertise as qualified according to law;
- business site, facilities, warehousing and sanitary environment compatible to the distributed pharmaceutical products;
- quality management system and personnel compatible to the distributed pharmaceutical products;
   and
- rules and regulations to ensure the quality of the distributed pharmaceutical products.

Operations of pharmaceutical distributors shall be conducted in accordance with the Pharmaceutical Operation Quality Management Rules and shall be granted a GSP certificate under such rules by the CFDA. A GSP certificate is valid for five years and may be renewed three months prior to its expiration date upon a reexamination by the relevant authority.

Pharmaceutical distributors must keep true and complete records of any pharmaceutical products purchased, distributed or sold with the generic name of such products, specification, approval code, term, manufacturer, purchasing or selling party, price and date of purchase or sale. A pharmaceutical distributor must keep such record at least until one year after the expiry date of such products and in any case, such record must be kept for no less than three years. Penalties may be imposed for any violation of record-keeping.

Pharmaceutical distributors can only distribute pharmaceutical products obtained from those with a Pharmaceutical Manufacturing Permit and a Pharmaceutical Distribution Permit.

On December 26, 2016, the Medical Reform Office of the State Council, the National Health and Family Planning Commission, the CFDA and other five government authorities promulgated the "Two-Invoice System" Opinions, which became effective on the same date. On April 25, 2017, the General Office of the State Council further promulgated the Notice on Issuing the Key Working Tasks for Deepening the Reform of Medicine and Health System in 2017. According to these rules, a two-invoice system is encouraged to be gradually adopted for drug procurement. The two-invoice system generally requires a drug manufacturer to issue only one invoice to its distributor followed by the distributor issuing a second invoice directly to the end customer hospital. Only one distributor is permitted to distribute drug products between the manufacturer and the hospital. The system also encourages manufacturers to sell drug products directly to hospitals. Public medical institutions are required to adopt the two-invoice system, and its full implementation nationwide is targeted for 2018. Pharmaceutical manufacturers and distributors who fail to implement the two-invoice system may be disqualified from attending future bidding events or providing distribution for hospitals and blacklisted for drug procurement practices. These rules aim to consolidate drug distribution and reduce drug prices.

Foreign Investment and "State Secret" Technology

The interpretation of certain PRC laws and regulations governing foreign investment and "state secret" technology is uncertain. Depending on the industry sectors, foreign investments are classified as "encouraged", "restricted" or "prohibited" under the Guidance Catalogue of Industries for Foreign Investment, or the Catalogue, published by the MOFCOM and the NDRC. Under the Catalogue, "manufacturing of modern Chinese medicines with confidential proprietary formula" has been deemed prohibited for any foreign investment. The technology and know-how of the She Xiang Bao Xin pill is classified as "state secret" technology by China's Ministry of Science and Technology, or the MOST, and the National Administration for the Protection of State Secrets, or NAPSS.

There are currently no PRC laws or regulations or official interpretations, and therefore there can be no assurance, as to whether the use of "state secret" technology constitutes the "manufacturing of Chinese medicines with confidential proprietary formula" under the Catalogue. However, under the Rules on Confidentiality of Science and Technology promulgated by the State Science and Technology Commission (the predecessor of the MOST and the NAPSS) on January 6, 1995, cooperation with foreign parties or establishing joint ventures with foreign parties in respect of state secret technology is expressly allowed, provided that such cooperation has been duly approved by the relevant science and technology authorities. The establishment of Shanghai Hutchison Pharmaceuticals as a sino-foreign joint venture, including the re-registration of licenses for She Xiang Bao Xin pills in its name, was approved by the local counterpart of the MOFCOM and the Shanghai Drug Administration in 2001. Subsequently, the "Confidential State Secret Technology" status protection for She Xiang Bao Xin pills was also granted in 2005 to Shanghai Hutchison Pharmaceuticals as a sino-foreign joint venture by the MOST and NAPSS. Consequently, we believe Shanghai Hutchison Pharmaceuticals is in compliance with all applicable PRC laws and regulations governing foreign investment and "state secret" technology and will continue to be so following our listing of our ADSs on the Nasdaq Global Select Market. Moreover, we believe that our other joint ventures and wholly-foreign owned enterprises in the PRC are also in compliance with all applicable PRC laws and regulations governing foreign investment and will continue to be so following our listing of our ADSs on the Nasdaq Global Select Market.

# U.S. Regulation of Pharmaceutical Product Development and Approval

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. The process of obtaining approvals and the subsequent compliance with appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement correspondence, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the U.S. Department of Justice, or DOJ, or other governmental entities. Drugs are also subject to other federal, state and local statutes and regulations.

Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

• completion of extensive pre-clinical studies, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA's GLP regulations;

- submission to the FDA of an IND application which must become effective before human clinical trials may begin and must be updated annually;
- IRB approval before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with study protocols, the applicable GCPs and other clinical trial-related regulations, to establish the safety and efficacy of the proposed drug product for its proposed indication;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA whether the NDA is acceptable
  for filing; if the FDA determines that the NDA is not sufficiently complete to permit substantive
  review, it may request additional information and decline to accept the application for filing until
  the information is provided;
- in-depth review of the NDA by FDA, which may include review by a scientific advisory committee;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug product are produced to assess compliance with the FDA's current good manufacturing practice requirements, or cGMP;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the NDA;
- payment of user fees and FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, such as REMS and post-approval studies required by FDA.

## Pre-clinical Studies

The data required to support an NDA is generated in two distinct development stages: pre-clinical and clinical. For new chemical entities, or NCEs, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the pre-clinical tests must comply with federal regulations, including GLPs. The sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor must resolve with the FDA any outstanding concerns or questions before the clinical trial can begin. Some long-term pre-clinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

### Clinical Studies

The clinical stage of development involves the administration of the drug product to human subjects or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that, in general, all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also reviews and approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. For example, information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase I, Phase II and Phase III clinical trials.

- Phase I: In a standard Phase I clinical trial, the drug is initially introduced into a small number of subjects who are initially exposed to a range of doses of the drug candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, appropriate dosing, side effect tolerability and safety of the drug.
  - Phase Ib: Although Phase I clinical trials are not intended to treat disease or illness, a Phase Ib trial is conducted in patient populations who have been diagnosed with the disease for which the study drug is intended. The patient population typically demonstrates a biomarker, surrogate, or other clinical outcome that can be assessed to show "proof-of-concept." In a Phase Ib study, proof-of-concept typically confirms a hypothesis that the current prediction of a biomarker, surrogate or other outcome benefit is compatible with the mechanism of action of the study drug.
  - Phase I/II: A Phase I and Phase II trial for the same treatment is combined into a single study
    protocol. The drug is administered first to determine a maximum tolerable dose, and then
    additional patients are treated in the Phase II portion of the study to further assess safety
    and/or efficacy.
- Phase II: The drug is administered to a limited patient population to determine dose tolerance and
  optimal dosage required to produce the desired benefits. At the same time, safety and further
  pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible
  adverse effects and safety risks and preliminary evaluation of efficacy.
- Phase III: The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well-controlled clinical trials to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall benefit/risk profile of the drug and provide an adequate basis for drug approval and labeling of the drug product. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a drug during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA. A pivotal study is a clinical study that adequately

meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the drug. Generally, pivotal studies are also Phase III studies but may be Phase II studies if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need. Post-approval trials, sometimes referred to as Phase 4 clinical trials, are conducted after initial regulatory approval, and they are used to collect additional information from the treatment of patients in the intended therapeutic indication or to meet other regulatory requirements. In certain instances, FDA may mandate the performance of Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and more frequently if serious adverse events occur. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk to human subjects. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. The FDA will typically inspect one or more clinical sites to assure compliance with GCPs and the integrity of the clinical data submitted. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

### NDA Submission and FDA Review Process

Following trial completion, trial results and data are analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling for the drug, information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support regulatory approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product to the satisfaction of the FDA. Under federal law, the submission of most NDAs is subject to the payment of an application user fees; a waiver of such fees may be obtained under certain limited circumstances. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric

subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by an application user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective through September 30, 2018, the user fee for an application requiring clinical data, such as an NDA, is \$2,421,495. PDUFA also imposes a program fee for prescription human drugs \$304,162. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA conducts a preliminary review of an NDA within 60 days of receipt and informs the sponsor by the 74th day after FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for a "priority review" NDA. The FDA does not always meet its PDUFA goal dates for standard and priority review NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality and purity. The FDA may refer applications for drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA may re-analyze the clinical trial data, which can result in extensive discussions between the FDA and us during the review process.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

If a drug receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a REMS to ensure that the benefits of a drug or biological product outweigh its risks. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

#### Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA, which authorizes FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. Section 505(b)(2) allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations relied upon to show that the drug is safe and effective for the intended use "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) authorizes NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain pre-clinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

### Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the pre-clinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." The Generic Drug User Fee Act (GDUFA), as reauthorized, sets forth

performance goals for FDA to review standard ANDA's within 10 months of their submission, and priority ANDA's within 8 months of their submission if they satisfy certain requirements.

Upon approval of an ANDA, the FDA indicates that the generic product is "therapeutically equivalent" to the RLD and it assigns a therapeutic equivalence rating to the approved generic drug in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider an "AB" therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, FDA's designation of an "AB" rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

## Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track Designation, accelerated approval, priority review and Breakthrough Therapy Designation, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. While these pathways can reduce the time it takes for the FDA to review an NDA, they do not guarantee that a product will receive FDA approval.

## **Fast Track Designation**

To be eligible for a Fast Track Designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast track designation determination within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with FDA, FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. A fast track drug also may be eligible for accelerated approval and priority review. In addition, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

### **Priority Review**

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of 10 months under current PDUFA guidelines. These 6- and 10-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for Fast Track Designation are also likely to be considered appropriate to receive a priority review.

## **Breakthrough Therapy Designation**

Under the provisions of the new Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted by Congress in 2012, a sponsor can request designation of a drug candidate as a

"breakthrough therapy," typically by the end of the drug's Phase II trials. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. For breakthrough therapies, the FDA may take certain actions, such as intensive and early guidance on the drug development program, that are intended to expedite the development and review of an application for approval.

### **Accelerated Approval**

FDASIA also codified and expanded on FDA's accelerated approval regulations, under which FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit over existing treatments based on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. A surrogate endpoint is a marker that does not itself measure clinical benefit but is believed to predict clinical benefit. This determination takes into account the severity, rarity or prevalence of the disease or condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform Phase 4 or post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, Fast Track Designation, priority review, accelerated approval and Breakthrough Therapy Designation, do not change the standards for approval and may not ultimately expedite the development or approval process.

### Pediatric Trials

Under PREA, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With the enactment of FDASIA, a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials, and/or other clinical development programs. The law requires the FDA to send a non-compliance letters to sponsors who do not submit their pediatric assessments as required.

Under the Best Pharmaceuticals for Children Act, or BPCA, certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor submits information requested by the FDA, relating to the use of the active moiety of the product candidate in children. Although the FDA may issue a

written request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population.

FDASIA permanently reauthorized PREA and BPCA, modifying some of the requirements under these laws, and established priority review vouchers for rare pediatric diseases.

## Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but the product will be entitled to orphan product exclusivity, meaning that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives regulatory approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity. The 21st Century Cures Act, which became law in December 2016, expanded the types of studies that qualify for orphan drug grants. Orphan drug designation also may qualify an applicant for federal tax credits relating to research and development costs.

## Post-Marketing Requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may legally prescribe drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the drug or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples also must comply with the U.S. Prescription Drug Marketing Act a part of the FDCA.

In the United States, once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that drugs be manufactured in specific approved facilities and in accordance with cGMP. Applicants may also rely on third parties for the production of clinical and commercial quantities of drugs, and these third parties must operate in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the

obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using third-party contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed or tested by them. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, risk minimization action plans and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug. Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development.

### Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Affordable Care Act. If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of drugs, total or partial

suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

## U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a NCE. A drug is a NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Specifically, the applicant must certify with respect to each relevant patent that: the required patent information has not been filed; the listed patent has expired; the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant. To the extent that the Section 505(b)(2) applicant relies on prior FDA findings of safety and efficacy, the applicant is

required to certify to the FDA concerning any patents listed for the previously approved product in the Orange Book to the same extent that an ANDA applicant would.

The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

#### Rest of the World Regulation of Pharmaceutical Product Development and Approval

For other countries outside of China and the United States, such as countries in Europe, Latin America or other parts of Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and ethical principles.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

#### Coverage and Reimbursement

#### PRC Coverage and Reimbursement

Historically, most of Chinese healthcare costs have been borne by patients out-of-pocket, which has limited the growth of more expensive pharmaceutical products. However, in recent years the number of people covered by government and private insurance has increased. According to the PRC National Bureau of Statistics, as of December 31, 2016, 744 million employees and residents in China were enrolled in the national medical insurance program, representing an increase of 78.1 million from December 31, 2015. The PRC government has announced a plan to give every person in China access to basic healthcare by year 2020.

### Reimbursement under the National Medical Insurance Program

The National Medical Insurance Program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. The State Council expects the pilot Urban Resident Basic Medical Insurance to cover the whole nation by 2010.

Participants of the National Medical Insurance Program and their employers, if any, are required to contribute to the payment of insurance premiums on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the National Medicines Catalogue. The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employees, jointly issued by several authorities including the Ministry of Labor and Social Security and the MOF, among others, on May 12, 1999, provides that a pharmaceutical product listed in the National Medicines Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements:

- it is set forth in the Pharmacopoeia of the PRC;
- it meets the standards promulgated by the CFDA; and
- if imported, it is approved by the CFDA for import.

Factors that affect the inclusion of a pharmaceutical product in the National Medicines Catalogue include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public.

The PRC Ministry of Labor and Social Security, together with other government authorities, has the power to determine the medicines included in the National Medicines Catalogue, which is divided into two parts, Part A and Part B. Provincial governments are required to include all Part A medicines listed on the National Medicines Catalogue in their provincial National Medicines Catalogue, but have the discretion to adjust upwards or downwards by no more than 15% from the number of Part B medicines listed in the National Medicines Catalogue. As a result, the contents of Part B of the provincial National Medicines Catalogues may differ from region to region in the PRC.

Patients purchasing medicines included in Part A of the National Medicines Catalogue are entitled to reimbursement of the entire amount of the purchase price. Patients purchasing medicines included in Part B of the National Medicines Catalogue are required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price. The percentage of reimbursement for Part B medicines differs from region to region in the PRC.

The total amount of reimbursement for the cost of medicines, in addition to other medical expenses, for an individual participant under the National Medical Insurance Program in a calendar year is capped at the amounts in such participant's individual account under such program. The amount in a participant's account varies, depending on the amount of contributions from the participant and his or her employer.

#### National Essential Medicines List

On August 18, 2009, MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Medicines List, which was later amended in 2015, and the Guidelines on the Implementation of the Establishment of the National Essential Medicines System, which aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National Essential Medicines List. MOH promulgated the National Essential Medicines List (Catalog for the Basic Healthcare Institutions) on August 18, 2009, and promulgated the revised National Essential Medicines List on March 13, 2013. According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in the National Essential Medicines List. The drugs listed in National Essential Medicines List shall be purchased by centralized tender process and shall be subject to the price control by the NDRC. Remedial drugs in the National Essential Medicines List are all listed in the National Medicines Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

#### Price Controls

According to the Pharmaceutical Administration Law and the Regulations of Implementation of the Law of the People's Republic of China on the Administration of Pharmaceuticals, pharmaceutical products are subject to fixed or directive pricing system or to be adjusted by the market. Those pharmaceutical products included in the National Medicines Catalogues and the National Essential Medicines List and those drugs the production or trading of which are deemed to constitute monopolies, are subject to price controls by the PRC government in the form of fixed retail prices or maximum retail prices. Manufacturers and distributors cannot set the actual retail price for any given price controlled product above the maximum retail price or deviate from the fixed retail price set by the government. The retail prices of pharmaceutical products that are subject to price controls are administered by the NDRC and provincial and regional price control authorities. From time to time, the NDRC publishes and updates a list of pharmaceutical products that are subject to price controls. According to the Notice Regarding Measures on Government Pricing of Pharmaceutical Products issued by NDRC effective on December 25, 2000, maximum retail prices for pharmaceutical products shall be determined based on a variety of factors, including production costs, the profit margins that the relevant government authorities deem reasonable, the product's type, and quality, as well as the prices of substitute pharmaceutical products.

Further, pursuant to the Notice Regarding Further Improvement of the Order of Market Price of Pharmaceutical Products and Medical Services jointly promulgated by the NDRC, the State Council Legislative Affairs Office and the State Council Office for Rectifying, the MOH, the CFDA, the MOFCOM, the MOF and Ministry of Labor and Social Security on May 19, 2006, the PRC government exercises price control over pharmaceutical products included in the National Medicines Catalogues and made an overall adjustment of their prices by reducing the retail price of certain overpriced pharmaceutical products and increasing the retail price of certain underpriced pharmaceutical products in demand for clinical use but that have not been produced in large quantities by manufacturers due to their low retail price level. In particular, the retail price charged by hospitals at the county level or above may not exceed 115% of the procurement cost of the relevant pharmaceutical products or 125% for Chinese herbal pieces.

On February 9, 2015, the General Office of the State Council issued the Guiding Opinion on Enhancing Consolidated Procurement of Pharmaceutical Products by Public Hospitals. The opinion encourages public hospitals to consolidate their demands and to play a more active role in the procurement of pharmaceutical products. Hospitals are encouraged to directly settle the prices of pharmaceutical products with manufacturers. Consolidated procurement of pharmaceutical products should facilitate hospital reform, reduce patient costs, prevent corrupt conducts, promote fair competition and induce the healthy growth of the pharmaceutical industry. According to the opinion, provincial tendering processes will continue to be used for the pricing of essential drugs and generic drugs with significant demands, and transparent multi-party price negotiation will be used for some patented drugs and exclusive drugs.

On April 26, 2014, the NDRC issued the Notice on Issues concerning Improving the Price Control of Low Price Drugs, or the Low Price Drugs Notice, together with the LPDL. According to the Low Price Drugs Notice, for drugs with relatively low average daily costs within the current government-guided pricing scope (low price drugs), the maximum retail prices set by the government were cancelled. Within the standards of average daily costs, the specific purchase and sale prices are fixed by the producers and operators based on the drug production costs, market supply and demand and market competition. The standards of average daily costs of low price drugs are determined by the NDRC in consideration of the drug production costs, market supply and demand and other factors and based on the current maximum retail prices set by the government (or the national average bid-winning retail prices where the government does not set the maximum retail prices) and the average daily dose calculated according to the package insert. The current standards for the daily cost of low price chemical pharmaceuticals and of low price

traditional Chinese medicine pharmaceuticals are less than RMB3.0 per day and RMB5.0 per day respectively.

On May 4, 2015, the NDRC, the National Health and Family Planning Commission, the CFDA, MOFCOM and three other departments issued Opinions on Promoting Drug Pricing Reform. Under these opinions, beginning on June 1, 2015, the restrictions on the prices of the drugs that were subject to government pricing were cancelled except for narcotic drugs and Class I psychotropic drugs which are still subject to maximum factory prices and maximum retail prices set by the NDRC. The medical insurance regulatory authority now has the power to prescribe the standards, procedures, basis and methods of the payment for drugs paid by medical insurance funds. The prices of patented drugs are set through transparent and public negotiation among multiple parties. The prices for blood products not listed in the National Medicines Catalogue, immunity and prevention drugs that are purchased by the Chinese government in a centralized manner, and AIDS antiviral drugs and contraceptives provided by the Chinese government for free, are set through a tendering process. Except as otherwise mentioned above, the prices for other drugs may be determined by the manufacturers and the operators on their own on the basis of production or operation costs and market supply and demand.

### Centralized Procurement and Tenders

The Guiding Opinions concerning the Urban Medical and Health System Reform, promulgated on February 21, 2000, aim to provide medical services with reasonable price and quality to the public through the establishment of an urban medical and health system. One of the measures used to realize this aim is the regulation of the purchasing process of pharmaceutical products by medical institutions. Accordingly, the MOH and other relevant government authorities have promulgated a series of regulations and releases in order to implement the tender requirements.

According to the Notice on Issuing Certain Regulations on the Trial Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on July 7, 2000 and the Notice on Further Improvement on the Implementation of Centralized Tender Procurement of Drugs by Medical Institutions promulgated on August 8, 2001, medical institutions established by county or higher level government are required to implement centralized tender procurement of drugs.

The MOH promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (for Trial Implementation), or the Centralized Procurement Regulations, on March 13, 2002, and promulgated Sample Document for Medical Institutions for Procurement of Drugs by Centralized Tender and Price Negotiations (for Trial Implementation), or the Centralized Tender Sample Document in November 2001, as amended in 2010, to implement the tender process requirements and ensure the requirements are followed uniformly throughout the country. The Centralized Tender Regulations and the Centralized Tender Sample Document provide rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. On January 17, 2009, the MOH, the CFDA and other four national departments jointly promulgated the Opinions on Further Regulating Centralized Procurement of Drugs by Medical Institutions. According to the notice, public medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products through centralized procurement. Each provincial government shall formulate its catalogue of drugs subject to centralized procurement. Specifically, the procurement could be achieved through public tendering, online bidding, centralized price negotiations and online competition platform. Except for drugs in the National Essential Medicines List (the procurement of which shall comply with the relevant rules on National Essential Medicines List), certain pharmaceutical products which are under the national government's special control and traditional Chinese medicines, in principle, all drugs used by public medical institutions shall be covered by the catalogue of drugs subject to centralized procurement. On July 7, 2010, the MOH and six other ministries and commissions jointly promulgated the Working Regulations of Medical Institutions for Centralized Procurement of Drugs to further regulate the centralized procurement of drugs and clarify the code of conduct of the parties in centralized drug procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralized tender process is in principle conducted once every year in all provinces and cities in China. Drug manufacturing enterprises, in principle, shall bid directly for the centralized tender process. Certain related parties, however, may be engaged to act as bidding agencies for the centralized tender process. Such intermediaries are not permitted to engage in the distribution of drugs and must have no conflict of interest with the organizing government agencies. The bids are assessed by a committee composed of pharmaceutical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, qualifications and reputation of the manufacturer, and after-sale services. Only pharmaceuticals that have won in the centralized tender process may be purchased by public medical institutions funded by government in the relevant region.

### U.S. Coverage and Reimbursement

Successful sales of our products or drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new product success. These third-party payors are increasingly reducing reimbursements for medical drugs and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Medicare payment for some of the costs of prescription drugs may increase demand for drugs for which we receive regulatory approval. However, any negotiated prices for our drugs covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures are made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, if third-party payors do not consider a drug to be cost-effective compared to other available therapies, they may not cover such drugs as a benefit under their plans or, if they do, the level of payment may not be sufficient.

The Affordable Care Act, enacted in March 2010, has had a significant impact on the health care industry. The Affordable Care Act expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. The Bipartisan Budget Act of 2018 made certain changes to Medicare Part D coverage, including changing the date when the Medicare Part D coverage gap is eliminated from 2020 to 2019, sunsetting the exclusion of biosimilars from the Medicare Part D coverage gap discount program in 2019 and reallocating responsibility for discounted pricing under the Medicare Part D coverage gap discount program from third-party payors to pharmaceutical companies. In December 2017, Congress also repealed the "individual mandate," which was an Affordable Care Act requirement that individuals obtain healthcare insurance coverage or face a penalty. This repeal could affect the total number of patients who have coverage from third-party payors that reimburse for use of our products.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted that affect reimbursement for prescription drugs. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013, and, due to subsequent legislative amendments, will stay in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, other proposed legislative and regulatory changes could affect reimbursement for prescription drugs. In January 2017, the Medicare Prescription Drug Price Negotiation Act was proposed in Congress, which would require the government to negotiate Medicare prescription drug prices with pharmaceutical companies. In October 2017, a similar bill, the Medicare Drug Price Negotiation Act of 2017 was proposed in Congress. In November 2017, the Centers for Medicare & Medicaid Services announced a Final Rule that would adjust the applicable payment rate as necessary for certain separately payable drugs and biologicals acquired under the 340B Program from average sales price plus 6% to average sales price minus 22.5%. Congress and the U.S. administration continue to evaluate other proposals that could affect third-party reimbursement for our drug candidates, if approved.

#### Rest of the World Coverage and Reimbursement

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal drugs for which their national health insurance systems provide reimbursement and to control the prices of medicinal drugs for human use. A member state may approve a specific price for the medicinal drug or it may instead adopt a system of direct or indirect controls on the profitability of our company placing the medicinal drug on the market. Historically, drugs launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

### Other Healthcare Laws

#### Other PRC Healthcare Laws

### Advertising of Pharmaceutical Products

Pursuant to the Provisions for Drug Advertisement Examination, which were promulgated on March 13, 2007 and came into effect on 1 May 2007, an enterprise seeking to advertise its drugs must apply for an advertising approval code. The validity term of an advertisement approval number for pharmaceutical drugs is one year. The content of an approved advertisement may not be altered without prior approval. Where any alteration to the advertisement is needed, a new advertisement approval number shall be obtained.

### Packaging of Pharmaceutical Products

According to the Measures for The Administration of Pharmaceutical Packaging, effective on September 1, 1988, pharmaceutical packaging must comply with the provisions of the national standard and professional standard. If there are no standards, the enterprise can formulate its own standard after obtaining the approval of the provincial level food and drug administration or bureau of standards. The enterprise shall reapply for the relevant authorities if it needs to change the packaging standard. Drugs without packing must not be sold in PRC (except for drugs needed by the army).

### Labor Protection

Under the Labor Law of the PRC, effective on January 1, 1995 and subsequently amended on August 27, 2009, the PRC Employment Contract Law, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008, employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the PRC.

Pursuant to the Law of Manufacturing Safety of the People's Republic of China effective on November 1, 2002 and subsequently amended on December 1, 2014, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws and regulations. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities.

Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process.

Pursuant to applicable PRC laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011, the Interim Regulations on the Collection and Payment of Social Security Funds which became effective on January 22, 1999, the Interim Measures concerning the Maternity Insurance which became effective on January 1, 1995 and the Regulations on Work-related Injury Insurance which became effective on January 1, 2004 and were subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance, and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make social insurance registration, the social insurance collecting authority will order the employer to correct within the prescribed time period. The relevant administrative department may impose a fine equivalent to three times the overdue amount and management personnel who are directly responsible can be fined RMB500 to RMB3,000 if the employer fails to correct within the prescribed time period.

### Commercial Bribery

Medical production and operation enterprises involved in criminal, investigation or administrative procedure for commercial bribery will be listed in the Adverse Records of Commercial Briberies by provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry enforced on March 1, 2014 by the National Health and Family Planning Commission, if medical production and operation enterprises are listed into the Adverse Records of Commercial Briberies for the first time, their production shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies in local province in two years from public of the record, and public medical institutions, and medical and health institutions receiving financial subsidies in other provinces shall lower their rating in bidding or purchasing process. If medical production and operation enterprises are listed into the Adverse Records of Commercial Briberies twice or more times in five years, their production may not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide in two years from public of the record.

As advised by our PRC legal advisor, from a PRC law perspective, a pharmaceutical company will not be penalized by the relevant PRC government authorities merely by virtue of having contractual relationships with distributors or third-party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third-party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third-party promoters, and will not be subject to penalties or sanctions by relevant PRC government authorities as a result of failure to monitor their operating activities.

#### Product Liability

In addition to the strict new drug approval process, certain PRC laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in the PRC. Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the PRC, or the PRC Civil Law, promulgated on April 12, 1986 and amended on August 27, 2009, 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 Product Quality Law of the PRC, or the Product Quality Law, was promulgated to supplement the PRC Civil Law aiming to define responsibilities for product quality, 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 amended by the Ninth National People's Congress on July 8, 2000 and was later amended by the Eleventh National People's Congress on August 27, 2009. Pursuant to the amended Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the PRC on the Protection of the Rights and Interests of Consumers was promulgated on October 13, 1993 and was amended on October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy which they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liabilities under applicable laws of the PRC if their goods or services lead to the death or injuries of customers or other third parties.

### PRC Tort Law

Under the Tort Law of the PRC which became effective on July 1, 2010, if damages to other persons are caused by defective products that are resulted from the fault of a third party such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as issuance of warning, recall of products, etc. in a timely manner. The producers or the sellers shall be liable under tort if they cause damages due to their failure to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced and sold with known defects, causing deaths or severe damage to the health of others, the infringed party shall have the right to claim respective punitive damages in addition to compensatory damages.

## Other PRC National- and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. Our hospital 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, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We also comply with numerous additional state 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, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

#### Other U.S. Healthcare Laws

We may also be subject to healthcare regulation and enforcement by the U.S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

#### Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

#### False Claims

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Analogous state law equivalents may apply and may be broader in scope than the federal requirements. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

### Payments to Physicians

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and submit reports to the government by March 31, 2014 and June 30, 2014, and the 90th day of each subsequent calendar year. Certain states also mandate implementation of compliance

programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

## Data Privacy and Security

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

## PRC Regulation of Foreign Currency Exchange, Offshore Investment and State-Owned Assets

## PRC Foreign Currency Exchange

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

- Foreign Currency Administration Rules (1996), as last amended on August 5, 2008, or the Exchange Rules; and
- Administration Rules of the Settlement, Sale and Payment of Foreign Exchange (1996), or the Administration Rules.

Under the Exchange Rules, the renminbi is convertible for current account items, including the distribution of dividends, interest payments, 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 SAFE.

Under the Administration Rules, foreign-invested enterprises 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 MOFCOM, the SAFE and the NDRC.

Pursuant to the Circular on Further Improving and Adjusting the Direct Investment Foreign Exchange Administration Policies, or Circular 59, promulgated by SAFE on November 19, 2012 and became effective on December 17, 2012, approval is not required for the opening of and payment into foreign exchange accounts under direct investment, for domestic reinvestment with legal income of foreign investors in China. Circular 59 also simplified the capital verification and confirmation formalities for Chinese foreign invested enterprises and the foreign capital and foreign exchange registration formalities required for the foreign investors to acquire the equities and foreign exchange registration formalities required for the foreign investors to acquire the equities of Chinese party and other items. Circular 59 further improved the administration on exchange settlement of foreign exchange capital of Chinese foreign invested enterprises.

### Foreign Exchange Registration of Offshore Investment by PRC Residents

In July 2014, SAFE issued the Notice on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Offshore Investment and Financing and Round Trip Investment via Special Purpose Vehicles, or Circular 37, and its implementation guidelines, which abolishes and supersedes the SAFE's Circular on Relevant Issues Concerning Foreign Exchange Administration for PRC Residents to Engage in Financing and Round Trip Investment via Overseas Special Purpose Vehicles, or Circular 75. Pursuant to Circular 37 and its implementation guidelines, PRC residents (including PRC institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle, or SPV, directly established or indirectly controlled by PRC residents for the purposes of offshore investment and financing with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such PRC residents are also required to amend their registrations with SAFE when there is a significant change to the SPV, such as changes of the PRC individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV. Failure to comply with the registration procedures set forth in Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or PRC residents to penalties under PRC foreign exchange administration regulations.

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies. Based on this regulation, directors, supervisors, senior management and other employees of domestic subsidiaries or branches of a company listed on an overseas stock market who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to a few exceptions, are required to register with the SAFE or its local counterparts by following certain procedures if they participate in any stock incentive plan of the company listed on an overseas stock market. Foreign exchange income received from the sale of shares or dividends distributed by the overseas listed company may be remitted into a foreign currency account of such PRC citizen or be exchanged into renminbi. Our PRC citizen employees who have been granted share options have been subject to these rules due to our listing on the AIM market of the London Stock Exchange and the listing of our ADSs on the Nasdaq Global Select Market.

### Regulation on Investment in Foreign-invested Enterprises

Pursuant to PRC law, the registered capital of a limited liability company is the total capital contributions subscribed for by all the shareholders as registered with the company registration authority. A foreign-invested enterprise also has a total investment limit that is approved by or filed with the MOFCOM or its local counterpart by reference to both its registered capital and expected investment scale. The difference between the total investment limit and the registered capital of a foreign-invested enterprise or the cross-border financing risk weighted balance calculated based on a formula by the PBOC represents the foreign debt financing quota to which it is entitled (i.e., the maximum amount of debt which the company may borrow from a foreign lender). A foreign-invested enterprise is required to obtain approval from or file with the MOFCOM or its local counterpart for any increases to its total investment limit. In accordance with these regulations, we and our joint venture partners have contributed financing to our PRC subsidiaries and joint ventures in the form of capital contributions up to the registered capital amount and/or in the form of shareholder loans up to the foreign debt quota. According to the financing needs of our PRC subsidiaries and joint ventures, we and our joint venture partners have requested and received approvals from the government authorities for increases to the total investment limit for certain of our PRC subsidiaries and joint ventures from time to time. As a result, these regulations have not had a material impact to date on our ability to finance such entities.

Regulation on Dividend Distribution

The principal regulations governing distribution of dividends paid by wholly foreign-owned enterprises include:

- Company Law of the PRC (1993), as amended in 1999, 2004, 2005 and 2013;
- Foreign Investment Enterprise Law of the PRC (1986), as amended in 2000 and 2016; and
- Implementation Rules for the Foreign Investment Enterprise Law (1990), as amended in 2001 and 2014.

Under these laws and regulations, foreign-invested enterprises in China may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise in China 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 until the accumulative amount of such reserves reach 50.0% of its registered capital. These reserves are not distributable as cash dividends. The board of directors of a foreign-invested enterprise has the discretion to allocate a portion of its after-tax profits to staff welfare and bonus funds, which may not be distributed to equity owners except in the event of liquidation.

### Filings and Approvals Relating to State-Owned Assets

Pursuant to applicable PRC state-owned assets administration laws and regulations, incorporating a joint venture that will have investments of assets that are both state-owned and non-state-owned and investing in an entity that was previously owned by a state-owned enterprise require the performance of an assessment of the relevant state-owned assets and the filing of the assessment results with the competent state-owned assets administration, finance authorities or other regulatory authorities and, if applicable, the receipt of approvals from such authorities.

Our joint venture partners were required to perform a state-owned asset assessment when Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan were incorporated and our joint venture partners contributed state-owned assets, and when we invested in Hutchison Sinopharm, which was previously wholly-owned by Sinopharm, a state-owned enterprise. In all three instances, our joint venture partners have informed us that they have duly filed the relevant state-owned asset assessment results with, and obtained the requisite approvals from, the relevant governmental authorities as required by the foregoing laws and regulations. Accordingly, we believe that such joint ventures are in full compliance with all applicable laws and regulations governing the administration of state-owned assets, although we are currently unable to obtain copies of certain filing and approval documents of our joint venture partners due to their internal confidentiality constraints. We have not received any notice of warning or been subject to any penalty or other disciplinary action from the relevant governmental authorities with respect to the applicable laws and regulations governing the administration of state-owned assets.

### C. Organizational Structure

Our organizational structure is set forth above under "—A. History and Development of the Company—Our Organizational Structure."

# D. Property, Plants and Equipment

We are headquartered in Hong Kong where we have our main administrative offices. Our joint ventures, Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan, operate two large-scale research and development and manufacturing facilities for which they have obtained land use rights and property ownership certificates.

Shanghai Hutchison Pharmaceuticals relocated to its current facility outside of Shanghai in September 2016, and it has an aggregate site area of approximately 78,000 square meters (compared to approximately 58,000 square meters for its old facility located in Shanghai). Shanghai Hutchison Pharmaceuticals agreed to surrender its land use rights for the property where its old production facility was located to the Shanghai government for cash consideration. The total cash and subsidies paid by the Shanghai government to Shanghai Hutchison Pharmaceuticals was approximately \$113 million, including approximately \$101 million for land compensation and \$12 million in government subsidies related to research and development projects.

Hutchison Baiyunshan's facility is in Guangzhou and has an aggregate site area of approximately 90,000 square meters. Hutchison Baiyunshan plans to sell its land use rights for an unused portion of its Guangzhou property to the local government for cash consideration. Hutchison Baiyunshan also operates two Chinese GAP-certified cultivation sites through its subsidiaries in Heilongjiang and Henan provinces in China. In December 2016, its subsidiary completed construction of new production facilities in Bozhou and production commenced in 2017.

Our and our joint ventures' manufacturing operations consist of bulk manufacturing and formulation, fill, and finishing activities that produce products and drug candidates for both clinical and commercial purposes. Our manufacturing capabilities have a large operation scale for our own-brand products. We and our joint ventures manufacture and sell about 4.6 billion doses of medicines a year, in the aggregate, through our well-established GMP manufacturing base. See "—Our Commercial Platform—Prescription Drugs Business—Shanghai Hutchison Pharmaceuticals" and "—Our Commercial Platform—Consumer Health Business—Hutchison Baiyunshan" for more details on our manufacturing operations.

Please also see "—Our Commercial Platform—Our Prescription Drugs Business—Shanghai Hutchison Pharmaceuticals" and "—Our Commercial Platform—Our Consumer Health Business—Hutchison Baiyunshan" for more details on the new facilities of Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan mentioned above.

Additionally, we rent and operate a 2,107 square meter manufacturing facility for fruquintinib in Suzhou, Jiangsu Province in Eastern China, and own a 5,024 square meter facility in Shanghai which houses research and development operations. We also lease 907 square meters of office space in Shanghai which houses Hutchison MediPharma's management and staff. In 2017, we entered into a new lease for a 6,129 square meter combined office and lab space in Shanghai to accommodate the anticipated growth of Hutchison MediPharma's management and staff and for a 2,246 square foot facility in Florham Park, New Jersey where we intend to house clinical and regulatory management and staff.

#### 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 together with Item 3.A. "Selected Financial Data," our consolidated financial statements and the related notes and our non-consolidated joint ventures' consolidated financial statements and the related notes appearing elsewhere in this annual report. This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," or similar language. All forward-looking statements included in this annual report are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. In evaluating our business, you should carefully consider the information provided under Item 3.D. "Risk Factors." Actual results could differ materially from those projected in the forward-looking statements. The terms "company," "Chi-Med," "we," "our" or "us" as used herein refer to Hutchison China MediTech Limited and its consolidated subsidiaries and joint ventures unless otherwise stated or indicated by context.

#### A. Operating Results.

#### Overview

We are an innovative biopharmaceutical company based in China aiming to become a global leader in the discovery, development and commercialization of targeted therapies for oncology and immunological diseases. Our approximately 360-person strong scientific team has created and developed a deep portfolio of eight drug candidates that are being investigated in active or completed clinical studies in 36 target patient populations around the world. These drug candidates are being developed to treat a wide spectrum of diseases, including solid tumors, hematological malignancies and cover immunology applications which we believe address significant unmet medical needs and represent large commercial opportunities. Many of these drugs have the potential to be first-in-class or best-in-class. Our success in research and development has led to partnerships with leading global pharmaceutical companies, including AstraZeneca, Eli Lilly and Nestlé Health Science.

As of December 31, 2017, we and our partners have invested about \$500 million in building our Innovation Platform. Since inception to December 31, 2017, our Innovation Platform's drug pipeline has dosed over 3,500 patients/subjects in clinical trials of our drug candidates as of December 31, 2017, with over 700 dosed in 2017, primarily driven by the six Phase III studies of savolitinib, fruquintinib and sulfatinib.

We have also established a profitable commercial infrastructure in China to market and distribute prescription drugs (under our Prescription Drugs business) and consumer health products (under our Consumer Health business) which together form our Commercial Platform. Net income attributable to our company generated from our Commercial Platform was \$25.2 million, \$70.3 million and \$40.0 million for the years ended December 31, 2015, 2016 and 2017, respectively. Net income attributable to our company generated from our Commercial Platform included one-time gains of \$40.4 million and \$2.5 million in the years ended December 31, 2016 and 2017, respectively, net of tax, from land compensation and other government subsidies paid to Shanghai Hutchison Pharmaceuticals by the Shanghai government. In addition to helping to fund our Innovation Platform, we anticipate that we will be able to utilize Shanghai Hutchison Pharmaceuticals and Hutchison Sinopharm, our Commercial Platform's two Prescription Drugs business joint ventures in which we nominate the management and run the day-to-day operations, to support the launch of products from our Innovation Platform if they are approved by the CFDA for use in China. Our Commercial Platform also includes our Consumer Health business, which is a profitable and cash flow generating business selling primarily over-the-counter pharmaceutical products (through our non-consolidated joint venture Hutchison Baiyunshan) and a range of health-focused consumer products.

Our consolidated revenue was \$178.2 million, \$216.1 million and \$241.2 million for the years ended December 31, 2015, 2016 and 2017, respectively. Net income attributable to our company was \$8.0 million and \$11.7 million for the years ended December 31, 2015 and 2016, respectively, compared to a net loss attributable to our company of \$26.7 million for the year ended December 31, 2017.

### **Basis of Presentation**

Our consolidated statements of operations data presented herein for the years ended December 31, 2017, 2016 and 2015 and our consolidated balance sheet data presented herein as of December 31, 2017 and 2016 have been derived from our audited consolidated financial statements, which were prepared in accordance with U.S. GAAP, and should be read in conjunction with those statements which are included elsewhere in this annual report.

Our Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan joint ventures under our Commercial Platform and our Nutrition Science Partners joint venture under our Innovation Platform are accounted for under the equity accounting method as non-consolidated entities in our consolidated

financial statements, and their consolidated financial statements were prepared in accordance with IFRS as issued by the IASB and included elsewhere in this annual report.

We have two strategic business units, our Innovation Platform and our Commercial Platform, that offer different products and services. Our Commercial Platform is further segregated into the two core business areas of Prescription Drugs and Consumer Health. The presentation of financial data for our business units excludes certain unallocated costs attributed to expenses incurred by our corporate head office. For more information on our corporate structure, see Item 4.A. "History and Development of the Company—Our Corporate Structure."

## Factors Affecting our Results of Operations

### Innovation Platform

# Research and Development Expenses

We believe our ability to successfully develop innovative drug candidates through our Innovation Platform will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Creating high quality global first-in-class or best-in-class drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of drug candidates has been steadily advancing and expanding, with eight clinical-stage drug candidates being investigated in active or completed clinical studies in 36 target patient populations in various countries, including six Phase III studies on savolitinib, fruquintinib and sulfatinib, and further clinical studies targeted to start in 2018. For more information on the nature of the efforts and steps necessary to develop our drug candidates, see Item 4.B. "Business Overview—Our Clinical Pipeline" and "Business Overview—Regulation."

All of the drug candidates of our Innovation Platform are still in development, and we have incurred and will continue to incur significant research and development costs for pre-clinical studies and clinical trials. We expect that our research and development expenses will significantly increase in future periods in line with the advance and expansion of the development of our drug candidates.

We and our collaboration partners have invested about \$500 million in our Innovation Platform as of December 31, 2017, with almost all of these funds used to pay for research and development expenses incurred for the development of our drug candidates. These expenses include:

- employee compensation related expenses, including salaries, benefits and equity compensation expense;
- expenses incurred for payments to CROs, investigators and clinical trial sites that conduct our clinical studies;
- the cost of acquiring, developing, and manufacturing clinical study materials;
- facilities, depreciation, and other expenses, which include office leases and other overhead expenses; and
- costs associated with pre-clinical activities and regulatory operations.

Research and development costs incurred by our Innovation Platform totaled \$47.4 million, \$66.9 million and \$75.5 million for the years ended December 31, 2015, 2016 and 2017, respectively, representing 26.6%, 31.0% and 31.3% of our total consolidated revenue for the respective period. These figures do not include payments made by our collaboration partners directly to third parties to help fund the research and development of our drug candidates.

We have historically been able to fund the research and development expenses for our Innovation Platform via a range of sources, including financial support provided by our collaboration partners, cash flows generated from and dividend payments from our Commercial Platform, the proceeds raised from our initial public offering on the AIM market of the London Stock Exchange, our initial public offering and follow-on offering on the Nasdaq Global Select Market, banks loans (some of which have been subject to guarantees or certain other arrangements by Hutchison Whampoa Limited, a subsidiary of CK Hutchison) and investments from other third-parties such as Mitsui.

This diversified approach to funding allows us to not depend on any one method of funding for our Innovation Platform, thereby reducing the risk that sufficient financing will be unavailable as we continue to accelerate the development of our drug candidates.

For more information on the research and development expenses incurred for the development of our drug candidates, see "—Key Components of Results of Operations—Research and Development Expenses."

## Our Ability to Commercialize Our Drug Candidates

Our ability to generate revenue from our drug candidates depends on our ability to successfully complete clinical trials for our drug candidates and obtain regulatory approvals for them in the United States, Europe, China and other major markets.

We believe that our risk-balanced strategy of focusing on developing tyrosine kinase inhibitors for novel but relatively well-characterized targets and for validated targets, in combination with our development of multiple drug candidates concurrently and testing them for multiple indications, enhances the likelihood that our research and development efforts will yield successful drug candidates. Nonetheless, we cannot be certain if any of our drug candidates will receive regulatory approvals. Even if such approvals are granted, we will need to thereafter establish manufacturing supply and engage in extensive marketing prior to generating any revenue from such drugs, and the ultimate commercial success of our drugs will depend on their acceptance by patients, the medical community and third-party payors and their ability to compete effectively with other therapies on the market.

As a first step towards commercialization, we have incurred a total of approximately \$9.8 million in capital expenditures between 2013 and 2017 to establish a GMP standard manufacturing (formulation) facility in Suzhou, China, which now produces Phase III clinical supplies and will be used to produce fruquintinib, as well as our other drugs, for commercial supply, if they receive regulatory approval.

The competitive environment is also an important factor with the commercial success of our potential global first-in-class products, such as savolitinib and HMPL-523, depending on whether we are able to gain regulatory approvals and quickly bring such products to market ahead of competing drug candidates being developed by other companies.

For our drug candidates where we retain all rights worldwide, which currently include sulfatinib, epitinib, theliatinib, HMPL-523, HMPL-689 and HMPL-453, if they remain unpartnered, we will be able to retain all the profits if any of them are successfully commercialized, though we will need to bear all the costs associated with such drug candidates. Conversely, as discussed below, for our drug candidates which are subject to collaboration partnerships, our collaboration partners provide funding for development of the drug candidates but are entitled to retain a significant portion of any revenue generated by such drug candidates.

### **Our Collaboration Partnerships**

Our results of operations have been, and we expect them to continue to be, affected by our collaborations with third parties for the development and commercialization of certain of our drug candidates. Currently, these mainly include savolitinib (collaboration with AstraZeneca), fruquintinib

(collaboration with Eli Lilly) and HM004-6599, a reformulation of HMPL-004 (collaboration with our joint venture partner Nestlé Health Science). In addition to providing us with invaluable technical expertise and organizational resources, the financial support provided by these collaborations has been critical to our ability to develop and quickly advance the pre-clinical and clinical studies of multiple drug candidates concurrently.

In particular, our partners cover a major portion of our research and development costs for drug candidates developed in collaboration with them. For example, under our collaboration agreement with AstraZeneca, it is responsible for a significant portion of the development costs for savolitinib. However, in August 2016 we and AstraZeneca amended our collaboration agreement whereby we agreed to contribute additional funding for the research and development of savolitinib in return for a larger share of the upside if and when savolitinib is approved. Under our collaboration agreement with Eli Lilly, it is responsible for a significant portion of all fruquintinib development costs in an indication after we have achieved proof-of-concept for such indication. We share the research and development costs for HMPL-004/HM004-6599 with Nestlé Health Science through our non-consolidated joint venture Nutrition Science Partners.

In addition, under our licensing, co-development and commercialization agreements, we received upfront payments upon our entry into such agreements and milestone payments upon the achievement of certain development, regulatory and commercial milestones as well as payments for our provision of research and development services for the relevant drug candidate. Revenue recognized in our consolidated financial statements from such agreements with third parties totaled \$44.1 million, \$26.4 million and \$26.3 million for the years ended December 31, 2015, 2016 and 2017, respectively. In addition, income from research and development services from both third parties and related parties totaled \$8.0 million, \$8.8 million and \$9.7 million for the years ended December 31, 2015, 2016 and 2017, respectively.

The achievement of milestones for our drug candidates, which is dependent on the outcome of clinical studies, is subject to a high degree of uncertainty and, as a result, we cannot reasonably estimate when we can expect to receive future milestone payments, or at all. For more information on our revenue recognition policies, see "—Critical Accounting Policies and Significant Judgments and Estimates—Revenue recognition for research and development projects." If we are unable to achieve development milestones for our drug candidates or if our partners were to terminate their collaborative agreements with us, payments for research and development services could also be affected.

Our collaboration partners are entitled to a significant proportion of any future revenue from commercialization of our drug candidates developed in collaboration with them, as well as a degree of influence over the clinical development process for such drug candidates. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all, which would affect our ability to receive additional upfront, milestone or service payments in the future. For more information regarding our collaboration agreements, see Item 4.B. "Business Overview—Overview of Our Collaborations."

#### Commercial Platform

## China Government Healthcare Spending and Drug Pricing Policies

Revenue of our Prescription Drugs business and our non-consolidated joint venture Hutchison Baiyunshan, part of our Consumer Health business, is directly affected by the sales volume and pricing of their own-brand prescription and over-the-counter pharmaceutical products as well as third-party pharmaceutical products. The principal activities of our Prescription Drugs business are described below under "—Ability of Prescription Drugs Business to Effectively Market Own-Brand and Third-Party Drugs." Hutchison Baiyunshan is a non-consolidated joint venture whose key products are two generic over-the-counter therapies, Fu Fang Dan Shen tablets, a treatment for chest congestion and angina pectoris, and Banlangen granules, an anti-viral treatment.

The sales volume of the products sold by these businesses is driven in part by the level of Chinese government spending on healthcare and the coverage of Chinese government medical insurance schemes, which is correlated with patient reimbursements for drug purchases, all of which have increased significantly in recent years as part of healthcare reforms in China. The sales volume of pharmaceutical products in China is also influenced by their representation on the Medicines Catalogue for the National Basic Medical Insurance, Labor Injury Insurance and Childbirth Insurance Systems in China, or the National Medicines Catalogue, which determines eligibility for drug reimbursement, as well as their representation on the National Essential Medicines List, which mandates distribution of drugs in China. Substantially all pharmaceutical products manufactured and sold by Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan in 2017 were capable of being reimbursed under the National Medicines Catalogue as of December 31, 2017.

In addition, among these two joint ventures an aggregate of 48 drugs, of which 15 were in active production as of December 31, 2017, have been included on the National Essential Medicines List. She Xiang Bao Xin pills, Shanghai Hutchison Pharmaceuticals' top-selling drug, is one of the few proprietary drugs included on the National Essential Medicines List. The National Medicines Catalogue and the National Essential Medicines List are subject to revision by the government from time to time, and our results could be materially and adversely affected if any products sold by our Prescription Drugs business or Hutchison Baiyunshan are removed from the National Medicines Catalogue or the National Essential Medicines List. For more information, see Item 3.D. "Risk Factors—Risks Related to Our Commercial Platform—Reimbursement may not be available for the products currently sold through our Commercial Platform or our drug candidates in China, the United States or other countries, which could diminish our sales or affect our profitability."

The sale prices of certain pharmaceutical products sold by our Commercial Platform joint ventures are also subject to Chinese government's price controls. In April 2014, the China National Development and Reform Commission, or the NDRC, announced a new Low Price Drug List, or LPDL, aimed at making certain low-price pharmaceuticals more profitable for manufacturers to produce. The LPDL established caps for the daily cost of chemical pharmaceuticals at less than RMB3.0 per day and of traditional Chinese medicine pharmaceuticals at less than RMB5.0 per day. The LPDL gives manufacturers flexibility to increase prices within the caps and exempts LPDL pharmaceuticals from hospital tenders. As of the end of 2017, Hutchison Baiyunshan's two top-selling products, Fu Fang Dan Shen tablets and Banlangen, cost consumers RMB1.7 per day and RMB1.6 per day, respectively, and Shanghai Hutchison Pharmaceuticals' two top-selling products, She Xiang Bao Xin pills and Danning tablets, cost RMB4.0 per day and RMB3.3 per day, respectively, well below the established caps for traditional Chinese medicine pharmaceuticals under the LPDL. As a result, we do not expect the LPDL to exert downward pressure on the pricing of these products unless the government makes significant downward adjustments to the LPDL price caps in the future.

Subject to customer demand, we have the ability to increase the prices for these products under the current LPDL price caps. For example, during 2016 we began to phase in, on a province-by-province basis, a 30% price increase for She Xiang Bao Xin pills from RMB2.7 per day to RMB3.5 per day and in 2017 we further increased the price to RMB4.0 per day. In addition, the pricing of Shanghai Hutchison Pharmaceuticals' prescription drugs are influenced by the outcomes of periodic provincial and municipal tender processes organized by the various provincial or municipal government agencies in China. For more information, see Item 4.B. "Business Overview—Coverage and Reimbursement."

## Ability of Prescription Drugs Business to Effectively Market Own-Brand and Third-Party Drugs

A key component of our Commercial Platform is the extensive marketing network of our Prescription Drugs business operated by our joint ventures Shanghai Hutchison Pharmaceuticals and Hutchison Sinopharm, which includes approximately 2,300 medical sales staff covering approximately 22,500 hospitals

in over 300 cities and towns in China. Our results of operations are affected by the degree to which this marketing network is successful in not only marketing its existing drugs but also new drugs either from third parties or developed by our Innovation Platform, if approved. Historically, the substantial majority of revenue from our Prescription Drugs business was generated from sales of She Xiang Bao Xin pills, which represented approximately 88% of its total revenue for the years ended December 31, 2015 and 2016 and approximately 86% of its total revenue for the year ended December 31, 2017.

In addition, since our acquisition of a 51% equity interest in Hutchison Sinopharm in April 2014, we have been in the process of migrating its operational focus from the legacy logistics and distribution business of a predecessor entity previously operated by our joint venture partner toward providing a distribution and commercialization service for drugs owned by third parties, which has a relatively higher profit margin.

In the second quarter of 2015, Hutchison Sinopharm became the exclusive first-tier distributor to distribute and market AstraZeneca's quetiapine tablets (under the Seroquel trademark), a medication to treat schizophrenia and bipolar disorder, in all of China. Under this arrangement, Hutchison Sinopharm manages the distribution and logistics for this drug and Shanghai Hutchison Pharmaceuticals markets it. In addition, Hutchison Sinopharm began to exclusively co-promote Merck Serono's bisoprolol fumarate tablets (under the Concor trademark), a beta-blocker to treat hypertension, in a few provinces in China in the first quarter of 2015. In January 2016, Hutchison Healthcare granted a license to Hutchison Sinopharm to distribute Chi-Med-owned Zhi Ling Tong infant nutrition products, which had previously been distributed by a third-party distributor.

Seroquel in particular represents a new therapeutic area for our medical sales representatives, and in the limited time since we commenced our services for these drugs, we have been successful in generating sales. During 2017, Shanghai Hutchison Pharmaceuticals had a dedicated medical sales team of about 120 people to support the commercialization of Seroquel.

China has begun implementing a new regulatory two-invoice system on a province-by-province basis. In principle, the purpose of the two-invoice system is to restrict the number of layers in the drug distribution system in China, in order to improve transparency, compliant business conduct and efficiency. The impact to us is that, starting in October 2017 and by the end of 2018, the original Seroquel sales model, in which our consolidated revenues reflect total gross sales of Seroquel, has begun to shift to a fee-for-service model similar to that used all along on Concor. Transactions under the fee-for-service model applies net accounting as Hutchison Sinopharm acts as a service provider and does not bear inventory risk as it no longer takes delivery of Seroquel. We expect that this change will reduce the top-line revenues Hutchison Sinopharm records from sales of Seroquel in future periods; but it will have no material impact on profitability and limited impact to our commercial team operations and expansion plans.

In the longer term, the ability of our marketing network to adapt to effectively market such drugs to doctors and hospitals, as well as other third-party drugs we may provide services for in the future and any oncology or immunology drugs from our Innovation Platform, will impact our revenue and profitability. In addition, if we are unsuccessful in marketing any third-party drugs, it may adversely affect our ability to enter into commercialization arrangements for additional drugs or prevent us from expanding the geographic scope of existing arrangements.

#### Seasonality

The results of operations of our Commercial Platform are also affected by seasonal factors. Our Commercial Platform typically experiences higher profits in the first half of the year due to the sale cycles of our distributors, whereby they typically increase their inventories at the beginning of each year. In addition, in the second half of each year, our Commercial Platform typically spends more on marketing

activities to help reduce such inventory held by distributors. We do not experience material seasonal variations in the results of our Innovation Platform.

## Overall Economic Growth and Consumer Spending Patterns

The results of operations and growth of our Consumer Health business depend in part on continuing economic growth and increasing income and health awareness of consumers in Asia. Although economic growth in China has slowed in recent periods, it achieved an annual growth rate in real gross domestic product of approximately 6.8% in 2017 according to the International Monetary Fund. As per capita disposable income has increased, consumer spending has also increased, and consumers in China have tended to be more health conscious and to spend more on organic and natural products for their families' health and well-being. However, if customer demand for such products does not achieve the levels we expect, whether due to slowing economic conditions, changing consumer tastes or otherwise, the results of operations and growth of our Consumer Health business could be materially and adversely affected.

## Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of operating results and financial condition are based upon our consolidated financial statements. The preparation of consolidated financial statements requires us to estimate the effect of various matters that are inherently uncertain as of the date of the consolidated financial statements. Each of these required estimates varies with regard to the level of judgment involved and its potential impact on our reported financial results. Estimates are deemed critical when a different estimate could have reasonably been used or where changes in the estimates are reasonably likely to occur from period to period, and a different estimate would materially impact our financial position, changes in financial position or results of operations. Our significant accounting policies are discussed under note 3 to our consolidated financial statements included in this annual report. We believe the following critical accounting policies are affected by significant judgments and estimates used in the preparation of our consolidated financial statements and that the judgments and estimates are reasonable.

### Revenue recognition for research and development projects

We recognize revenue for the performance of services when each of the following four criteria are met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

We have entered into research and developments agreements with collaborative partners for the research and development of drug products. The terms of the agreements may include non-refundable upfront and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. We estimate the selling price for each unit of accounting and allocate the arrangement consideration to each unit utilizing the relative selling price method.

We determine the estimated selling price for deliverables within each agreement using vendor-specific objective evidence of selling price, if available, or third-party evidence of selling price if vendor-specific objective evidence is not available, or our best estimate of selling price if neither vendor-specific objective evidence nor third-party evidence is available. Determining the best estimate of selling price for a deliverable requires significant judgment. Our process for determining the best estimate of selling price

involves management's judgment. Our process considers multiple factors such as discounted cash flows, estimated expenses and other costs and available data, which may vary over time, depending upon the circumstances, and relate to each deliverable. If the estimated obligation period of one or more deliverables should change, the future amortization of the revenue would also change. Revenue allocated to an individual element is recognized when all other revenue recognition criteria are met for that element.

These collaborative and other agreements may contain milestone payments. Revenues from milestones, if they are considered substantive, are recognized upon successful accomplishment of the milestones. Determining whether a milestone is substantive involves judgment, including an assessment of our involvement in achieving the milestones and whether the amount of the payment is commensurate to our performance. If not considered substantive, milestones are initially deferred and recognized over the remaining period of the performance obligation.

We recognize a contingent milestone payment as revenue in its entirety upon our achievement of the milestone. A milestone is substantive if the consideration earned from the achievement of the milestone (i) is consistent with performance required to achieve the milestone or the increase in value to the delivered item; (ii) relates solely to past performance; and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement.

### **Share-based Compensation**

We account for share-based compensation by measuring and recognizing compensation expense for share options made to employees and directors based on the estimated grant date fair values. We used the graded vesting method to allocate compensation expense to reporting periods over each optionee's requisite service period.

We estimate the fair value of share options to employees and directors using the Polynomial model. Determining the fair value of share options requires the use of highly subjective assumptions, including volatility, risk free interest rate, dividend yield and the fair value of the underlying ordinary shares on the dates of grant or the dates of modification, among other inputs. The assumptions in determining the fair value of share options represent our best estimates, which involve inherent uncertainties and the application of judgment. As a result, if factors change and different assumptions are used, our level of share-based compensation could be materially different in the future. We have adopted Accounting Standards Update, or ASU, 2016-09, Improvements to Employee Share-Based Payment Accounting on January 1, 2017. This guidance permitted us to make an accounting policy election to account for forfeitures as they occur. We have adopted using the modified retrospective approach as required, and there was no cumulative effect adjustment. Prior to January 1, 2017, we applied an estimated forfeiture rate derived from historical and expected future employee termination behavior.

### Impairment of long-lived property, plant and equipment and other definite life intangible assets

We assess property, plant and equipment and other definite life intangible assets for impairment when events or changes in circumstances indicate that the carrying value of the assets or the asset grouping may not be recoverable. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a business or product line in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. We measure the recoverability of assets that we will continue to use in our operations by comparing the carrying value of the asset grouping to our estimate of the related total future undiscounted net cash flows. If an asset grouping's carrying value is not recoverable through the related undiscounted cash flows, the asset grouping is considered to be impaired. We measure the impairment by comparing the difference between the asset grouping's carrying value and its fair value. Property, plant and equipment and other definite life intangible assets are considered non-financial assets and are recorded at fair value only if an impairment charge is recognized.

Impairments are determined for groups of assets related to the lowest level of identifiable independent cash flows. When we determine that the useful lives of assets are shorter than we had originally estimated, we accelerate the rate of depreciation over the assets' new, shorter useful lives.

# Impairment of Goodwill

Goodwill is recorded when the purchase price of an acquisition exceeds the fair value of the net tangible and identified intangible assets acquired. Goodwill is allocated to our reporting units based on the relative expected fair value provided by the acquisition. Reporting units may be operating segments as a whole or an operation one level below an operating segment, referred to as a component. The goodwill is attributable to the Prescription Drugs and Consumer Health (PRC) business under the Commercial Platform.

We perform an annual impairment assessment in the fourth quarter of each year, or more frequently if indicators of potential impairment exist, to determine whether it is more likely than not that the fair value of a reporting unit in which goodwill resides is less than its carrying value. For reporting units in which this assessment concludes that it is more likely than not that the fair value is more than its carrying value, goodwill is not considered impaired and we are not required to perform the goodwill impairment test. Qualitative factors considered in this assessment include industry and market considerations, overall financial performance, and other relevant events and factors affecting the reporting unit. Additionally, as part of this assessment, we may perform a quantitative analysis to support the qualitative factors above by applying sensitivities to assumptions and inputs used in measuring a reporting unit's fair value. For reporting units in which the impairment assessment concludes that it is more likely than not that the fair value is less than its carrying value, we perform the goodwill impairment test, which compares the fair value of the reporting unit to its carrying value. If the fair value of the reporting unit exceeds the carrying value of the net assets assigned to that reporting unit, goodwill is not considered impaired. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, an impairment loss shall be recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit.

Our goodwill impairment test uses the income method to estimate a reporting unit's fair value. The income method is based on a discounted future cash flow approach that uses the following assumptions and inputs: revenue, based on assumed market segment growth rates; estimated costs; and appropriate discount rates based on a reporting unit's weighted average cost of capital as determined by considering the observable weighted average cost of capital of comparable companies. Our estimates of market segment growth and costs are based on historical data, various internal estimates, and a variety of external sources. These estimates are developed as part of our routine long-range planning process. We test the reasonableness of the inputs and outcomes of our discounted cash flow analysis against available comparable market data. A reporting unit's carrying value represents the assignment of various assets and liabilities, excluding certain corporate assets and liabilities, such as cash, investments, and debt. We performed the goodwill impairment test and determined that the fair values of the reporting units exceeded their carrying values and considered that impairment was not necessary for any reporting unit.

We have adopted ASU 2017-04, Simplifying the Accounting for Goodwill Impairment for annual goodwill impairment tests performed on testing dates after January 1, 2017. This guidance removes Step 2 of the goodwill impairment test, which required the estimation of an implied fair value of goodwill in the same manner as the amount of goodwill recognized in a business combination. For prior years' annual goodwill impairment tests, we determined that the fair values of the reporting units exceeded their carrying values and Step 2 has never been required.

#### Impairment of equity method investments

Our equity method investments represent our investments in our non-consolidated joint ventures. All of these are in non-marketable equity investments. Non-marketable equity investments are inherently risky, and their success depends on their ability to generate revenues, remain profitable, operate efficiently and raise additional funds and other key business factors. The companies could fail or not be able to raise additional funds when needed, or they may receive lower valuations with less favorable investment terms. These events could cause our investments to become impaired. In addition, financial market volatility could negatively affect our ability to realize value in our investments through liquidity events such as initial public offerings, mergers, and private sales.

We consider if our equity method investments are impaired when events or circumstances suggest that their carrying amounts may not be recoverable. An impairment charge would be recognized in earnings for a decline in value that is determined to be other-than-temporary. This is based on our quantitative and qualitative analysis, which includes assessing the severity and duration of the impairment and the likelihood of recovery before disposal. The investments are recorded at fair value only if impairment is recognized. The recognition of impairment and measurement of fair value requires significant judgment and includes a qualitative and quantitative analysis of events or circumstances that impact the fair value of the investment. Qualitative analysis of our investments involves understanding our investee's revenue and earnings trends relative to pre-defined milestones and overall business prospects, the technological feasibility of our investee's products and technologies, the general market conditions in the investee's industry or geographic area including adverse regulatory or economic changes, and the management and governance structure of the investee. We performed the qualitative and quantitative analysis and determined that events or circumstances did not suggest that the carrying amount of each of our equity method investments may not be recoverable and that impairment was not necessary.

## **Key Components of Results of Operations**

#### Revenue

We derive our consolidated revenue primarily from (i) licensing and collaboration projects conducted by our Innovation Platform, which generates revenue in the form of upfront payments, milestone payments and the payments received for providing research and development services for our collaboration projects and for other third parties and related parties; and (ii) the sales by our Commercial Platform, which generates revenue from the distribution and marketing of prescription pharmaceutical products by our Prescription Drugs business and consumer health products by our Consumer Health business.

The following table sets forth the components of our consolidated revenue for the years indicated, which does not include the revenue from our Commercial Platform's non-consolidated joint ventures, Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan. Our revenue from sales to related parties is attributable to sales by our Commercial Platform to indirect subsidiaries of CK Hutchison. Our revenue from research and development projects for related parties is attributable to income for research

and development services that we receive primarily from Nutrition Science Partners, our non-consolidated joint venture with Nestlé Health Science.

Year Ended December 31,								
20	17	20	16	6 201				
\$'000	%	\$'000	%	\$'000	%			
26,315	10.9	26,444	12.2	44,060	24.7			
	_	355	0.2	2,573	1.5			
9,682	4.0	8,429	3.9	5,383	3.0			
35,997	14.9	35,228	16.3	52,016	29.2			
196,720	81.6	171,058	79.2	118,113	66.3			
8,486	3.5	9,794	4.5	8,074	4.5			
205,206	85.1	180,852	83.7	126,187	70.8			
241,203	100.0	216,080	100.0	178,203	100.0			
	\$'000 26,315 9,682 35,997 196,720 8,486 205,206	26,315 10.9 9,682 4.0 35,997 14.9 196,720 81.6 8,486 3.5 205,206 85.1	2017     20       \$'000     %       \$'000     \$'000       26,315     10.9     26,444       —     —     355       9,682     4.0     8,429       35,997     14.9     35,228       196,720     81.6     171,058       8,486     3.5     9,794       205,206     85.1     180,852	2017     2016       \$'000     %       26,315     10.9     26,444     12.2       —     —     355     0.2       9,682     4.0     8,429     3.9       35,997     14.9     35,228     16.3       196,720     81.6     171,058     79.2       8,486     3.5     9,794     4.5       205,206     85.1     180,852     83.7	\$'000         %         \$'000         %         \$'000           26,315         10.9         26,444         12.2         44,060           —         —         355         0.2         2,573           9,682         4.0         8,429         3.9         5,383           35,997         14.9         35,228         16.3         52,016           196,720         81.6         171,058         79.2         118,113           8,486         3.5         9,794         4.5         8,074           205,206         85.1         180,852         83.7         126,187			

Our Innovation Platform's revenue primarily comprises revenue recognized in our consolidated financial statements under licensing, co-development and commercialization agreements for upfront and milestone payments for our drug candidates developed in collaboration with, among others, AstraZeneca and Eli Lilly, as well as income from research and development services that we receive from certain of our partners, including, among others, AstraZeneca and Eli Lilly as well as Nutrition Science Partners, our non-consolidated joint venture with Nestlé Health Science. Our Innovation Platform revenue also includes income from research and development services provided to other third parties and related parties, which are not related to our licensing and collaboration agreements.

The following table sets forth the components of our consolidated revenue contributed by the two core business areas of our Commercial Platform, namely Prescription Drugs and Consumer Health, for the years indicated.

	Year Ended December 31,								
	20	17	20	16	201				
	\$'000	%	\$'000	%	\$'000	%			
Revenue from Commercial Platform									
Prescription Drugs	166,435	81.1	149,861	82.9	105,478	83.6			
Consumer Health	38,771	18.9	30,991	17.1	20,709	16.4			
Total	205,206	100.0	180,852	100.0	126,187	100.0			

Our Prescription Drugs business's revenue primarily comprises revenue from the logistics and distribution business of our consolidated Hutchison Sinopharm joint venture with Sinopharm, a leading distributor of pharmaceutical and healthcare products and a leading supply chain service provider in China.

The revenue of our Prescription Drugs business's non-consolidated joint venture, Shanghai Hutchison Pharmaceuticals, the accounts of which are prepared in accordance with IFRS as issued by the IASB and whose revenue is not included in our consolidated revenue, was \$181.1 million, \$222.4 million and \$244.6 million for the years ended December 31, 2015, 2016 and 2017, respectively. Shanghai Hutchison Pharmaceuticals is a joint venture with Shanghai Pharmaceuticals, a leading pharmaceuticals company in

China, and primarily focuses on the manufacture and sale of prescription pharmaceutical products in China. We and Shanghai Pharmaceuticals each own 50% of this joint venture. We have the right to nominate the general manager and other management of this joint venture and run its day-to-day operations. The effect of Shanghai Hutchison Pharmaceuticals on our consolidated financial results is discussed below under "—Equity in Earnings of Equity Investees."

Our Consumer Health business's revenue primarily comprises revenue from sales of organic and natural products by Hutchison Hain Organic, our 50% consolidated joint venture with Hain Celestial, a Nasdaq-listed, natural and organic food and personal care products company. We consolidate the results of this joint venture into our results of operations as we own 50% of its equity and hold an additional casting vote in the event of a deadlock. Our Consumer Health business's revenue is also comprised of revenue from sales of Zhi Ling Tong infant nutrition products manufactured by Hutchison Healthcare, our wholly owned subsidiary, and distributed through Hutchison Sinopharm, and certain third-party consumer products distributed and marketed by Hutchison Consumer Products, a wholly owned subsidiary.

The revenue of our Consumer Health business's non-consolidated joint venture, Hutchison Baiyunshan, the accounts of which are prepared in accordance with IFRS as issued by the IASB and which revenue is not included in our consolidated revenue, was \$211.6 million, \$224.1 million and \$227.4 million for the years ended December 31, 2015, 2016 and 2017, respectively. Hutchison Baiyunshan is a joint venture with Guangzhou Baiyunshan, a leading China-based pharmaceutical company, and primarily focuses on the manufacture and distribution of over-the-counter pharmaceutical products in China. Our interest in Hutchison Baiyunshan is held through an 80%-owned subsidiary of ours, Hutchison BYS (Guangzhou) Holding Limited, which owns 50% of that joint venture, with the other 50% interest held by Guangzhou Baiyunshan. The effect of Hutchison Baiyunshan on our consolidated financial results are discussed under "—Equity in Earnings of Equity Investees."

## Cost of Sales and Operating Expenses

Cost of Sales

Our cost of sales are primarily attributable to the cost of sales of our Prescription Drugs business's consolidated Hutchison Sinopharm joint venture as well as the cost of sales of our Consumer Health business. Our cost of sales to related parties is attributable to sales by our Consumer Health business to indirect subsidiaries of CK Hutchison. The following table sets forth the components of our cost of sales attributable to third parties and related parties for the years indicated.

	Year Ended December 31,									
	20	17	20	16	20	15				
	\$'000	%	\$'000	%	\$'000	%				
Cost of Sales										
Costs of sales—third										
parties	169,764	96.6	149,132	95.4	104,859	94.7				
Costs of sales—related										
parties	6,056	3.4	7,196	4.6	5,918	5.3				
Total	175,820	100.0	156,328	100.0	110,777	100.0				

The following table sets forth the components of our cost of sales attributable to the two core business areas of our Commercial Platform, namely Prescription Drugs and Consumer Health, for the years indicated.

	Year Ended December 31,									
	201	2017		16	20	15				
	\$'000	%	\$'000	%	\$'000	%				
Cost of Sales										
Prescription Drugs	151,521	86.2	136,090	87.1	96,927	87.5				
Consumer Health	24,299	13.8	20,238	12.9	13,850	12.5				
Total	175,820	100.0	156,328	100.0	110,777	100.0				

Our Prescription Drugs business's cost of sales primarily comprises the cost of sales and transportation costs incurred by the legacy logistics and distribution activities of Hutchison Sinopharm, which commenced operations in April 2014, as well as the third-party drugs distribution and commercialization business of Hutchison Sinopharm beginning in the first quarter of 2015.

Our Consumer Health business's cost of sales primarily comprises the cost of goods sold by Hutchison Hain Organic, which purchases its product inventory from Hain Celestial for distribution in Asian markets, as well as the cost of goods sold, contract packing and transportation costs incurred by Hutchison Healthcare and Hutchison Consumer Products.

## Research and Development Expenses

Our research and development expenses are attributable to our Innovation Platform. These costs primarily comprise the cost of research and development and clinical trials for our drug candidates, including personnel compensation and related costs, clinical trial related costs such as payments to third-party CROs, and other research and development costs. The following table sets forth the components of our research and development expenses for the years indicated.

	Year Ended December 31,						
	201	17	20	16	20	15	
	\$'000	%	\$'000	%	\$'000	%	
R&D Expenses							
Innovation Platform:							
Personnel compensation and related costs	24,848	32.9	21,698	32.4	17,339	36.6	
Clinical trial related costs	45,250	59.9	38,589	57.7	24,690	52.1	
Other costs	5,425	7.2	6,584	9.9	5,339	11.3	
Total	75,523	100.0	66,871	100.0	47,368	100.0	

The following table summarizes for the years indicated the research and development expenses incurred for the development of our main drug candidates as well as the personnel compensation and other research and development related costs incurred by our Innovation Platform.

	Year Ended December 31,						
	201	17	201	16	201	15	
	\$'000	%	\$'000	%	\$'000	%	
Savolitinib (targeting c-Met)	9,146	12.1	4,945	7.4	2,419	5.1	
Fruquintinib (targeting VEGFR1/2/3)	15,660	20.7	12,908	19.3	12,951	27.3	
Sulfatinib (targeting VEGFR/FGFR1/CSF-1R)	7,726	10.2	10,815	16.2	6,105	12.9	
Epitinib (targeting EGFRm+ with brain							
metastasis)	3,141	4.2	1,994	3.0	629	1.3	
Theliatinib (targeting EGFR wild-type)	1,023	1.4	699	1.0	397	0.8	
HMPL-523 (targeting Syk)	1,875	2.5	4,112	6.2	2,880	6.1	
HMPL-689 (targeting PI3Kδ)	1,140	1.5	2,084	3.1	1,587	3.4	
HMPL-453 (targeting FGFR)	1,558	2.1	1,231	1.8	593	1.3	
Others and government grant	3,981	5.2	(199)	(0.3)	(2,871)	(6.1)	
Total clinical trial related costs	45,250	59.9	38,589	57.7	24,690	52.1	
Personnel compensation and related costs	24,848	32.9	21,698	32.4	17,339	36.6	
Other costs	5,425	7.2	6,584	9.9	5,339	11.3	
Total R&D expenses	75,523	100.0	66,871	100.0	47,368	100.0	

In addition to the research and development costs shown above, the table below summarizes the research and development costs incurred by our non-consolidated Nutrition Science Partners joint venture, primarily in relation to the development of our drug candidate HMPL-004/HM004-6599. The losses incurred by this joint venture during the periods indicated were reflected on our consolidated statements of operations in the equity in earnings of equity investees line item. The consolidated financial statements of Nutrition Science Partners are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report. For more information on this joint venture, see "—Equity in Earnings of Equity Investees."

	Year Ended December 31,						
	201	7	201	6	201	15	
	\$'000	%	\$'000	%	\$'000	%	
<b>Nutrition Science Partners</b>							
HMPL-004/HM004-6599 related development							
costs	(1,844)	20.0	(1,180)	16.0	(3,512)	46.5	
Other research costs	(7,366)	80.0	(7,302)	84.0	(4,040)	53.5	
Loss for the year	(9,210)	100.0	(8,482)	100.0	(7,552)	100.0	
Equity in earnings of equity investee							
attributable to our company	(4,605)	50.0	(4,241)	50.0	(3,776)	50.0	

We cannot determine with certainty the duration and completion costs of the current or future pre-clinical or clinical studies of our drug candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our drug candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our drug candidates. The

duration, costs, and timing of clinical studies and development of our drug candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of our ongoing as well as any additional clinical studies and other research and development activities;
- future clinical study results;
- uncertainties in clinical study enrollment rate;
- · significant and changing government regulation; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For more information on the risks associated with the development of our drug candidates, see Item 3.D. "Risk Factors—Risks Related to Our Innovation Platform—All of our drug candidates are still in development. If we are unable to obtain regulatory approval and ultimately commercialize our drug candidates or experience significant delays in doing so, our business will be materially harmed."

# Selling Expenses

The following table sets forth the components of our selling expenses for each of our business units for the years indicated.

	Year Ended December 31,							
	2017		20	16	20	15		
	\$'000	%	\$'000	%	\$'000	%		
Selling Expenses								
Commercial Platform:								
Prescription Drugs	9,981	51.7	9,592	53.3	6,635	65.0		
Consumer Health	9,341	48.3	8,406	46.7	3,574	35.0		
Total	19,322	100.0	17,998	100.0	10,209	100.0		

Our selling expenses primarily comprise sales and marketing expenses and related personnel expenses incurred by the Prescription Drugs and Consumer Health businesses of our Commercial Platform in their distribution and marketing of pharmaceutical and consumer health products.

## Administrative Expenses

The following table sets forth the components of our administrative expenses for each of our business units for the years indicated. Administrative expenses are also incurred by our corporate head office, which are not allocated to our business units.

	Year Ended December 31,						
	20	17	20	16	20	15	
	\$'000	%	\$'000	%	\$'000	%	
Administrative Expenses							
Innovation Platform	6,617	27.6	5,373	24.9	5,116	26.1	
Commercial Platform:							
Prescription Drugs	1,863	7.8	1,856	8.6	1,465	7.5	
Consumer Health	1,640	6.8	1,418	6.6	2,301	11.7	
Corporate Head Office	13,835	57.8	12,933	59.9	10,738	54.7	
Total	23,955	100.0	21,580	100.0	19,620	100.0	

Our Innovation Platform's administrative expenses primarily comprise the salaries and benefits of administrative staff, office leases and other overhead expenses incurred by our Innovation Platform.

Our Prescription Drug business's administrative expenses primarily comprise the salaries and benefits of administrative staff, office leases and other overhead expenses incurred by Hutchison Sinopharm.

Our Consumer Health business's administrative expenses primarily comprise the salaries and benefits of administrative staff, office lease and other overhead expenses incurred by Hutchison Hain Organic and Hutchison Healthcare and, to a lesser extent, Hutchison Consumer Products.

Our corporate head office administrative expenses, which are not allocated to our business units, primarily comprise the salaries and benefits of our corporate head office employees and directors, office leases and other overhead expenses.

# **Equity in Earnings of Equity Investees**

We have historically derived a significant portion of our net income from continuing operations from our equity in earnings of equity investees, which was primarily attributable to two of our Commercial Platform's non-consolidated joint ventures, Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan, partially offset by losses at our Innovation Platform's non-consolidated joint venture, Nutrition Science Partners. Our equity in earnings of equity investees (net of tax) contributed by the non-consolidated joint ventures from our Commercial Platform, Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan, was \$26.3 million, \$70.5 million and \$38.2 million for the years ended December 31, 2015, 2016 and 2017, respectively. Equity in earnings of Shanghai Hutchison Pharmaceuticals included one-time gains of \$40.4 million and \$2.5 million in the years ended December 31, 2016 and 2017, respectively, net of tax, from land compensation and other government subsidies paid to Shanghai Hutchison Pharmaceuticals by the Shanghai government.

Our equity in earnings of equity investees (net of tax) contributed by our Innovation Platform was losses of \$3.8 million, \$4.2 million and \$4.5 million for the years ended December 31, 2015, 2016 and 2017, respectively, which were primarily attributable to losses at Nutrition Science Partners, which has historically incurred significant losses attributable to research and development expenses and the cost of clinical trials for the drug candidate HMPL-004/HM004-6599.

Revenue of Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan are mainly affected by the sales volume and pricing of their prescription and over-the-counter pharmaceutical products. For more information on the factors affecting our Commercial Platform, see "—Factors Affecting Our Results of Operations—Commercial Platform." Nutrition Science Partners had no revenue for the years ended December 31, 2015, 2016 and 2017. The consolidated financial statements of Shanghai Hutchison Pharmaceuticals, Hutchison Baiyunshan and Nutrition Science Partners are presented separately elsewhere in this annual report.

The following table shows the revenue of these three non-consolidated joint ventures for the years indicated. The consolidated financial statements of these joint ventures are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report.

	Year Ended December 31,						
	20	17	2016		20	15	
	\$'000	%	\$'000	%	\$'000	%	
Revenue							
Innovation Platform:							
Nutrition Science Partners	_	_	_	_	_	_	
Commercial Platform:							
Shanghai Hutchison Pharmaceuticals	244,557	51.8	222,368	49.8	181,140	46.1	
Hutchison Baiyunshan	227,422	48.2	224,131	50.2	211,603	53.9	
Total	471,979	100.0	446,499	100.0	392,743	100.0	

The following table shows the amount of equity in earnings of equity investees (net of tax), and as a percentage of our total consolidated revenue, of our non-consolidated joint ventures for the years indicated.

	Year Ended December 31,							
	2017	7	2016		2015			
	\$'000	%	\$'000	%	\$'000	%		
Equity in earnings of equity investees,								
net of tax								
Innovation Platform:								
Nutrition Science Partners	(4,605)	(1.9)	(4,241)	(1.9)	(3,776)	(2.1)		
Others	58	0.0	47	0.0	6	0.0		
Commercial Platform:								
Shanghai Hutchison Pharmaceuticals	27,812	11.5	60,250	27.9	15,654	8.8		
Hutchison Baiyunshan	10,388	4.3	10,188	4.7	10,688	6.0		
Total	33,653	13.9	66,244	30.7	22,572	12.7		

# Operating Profit/(Loss)

Our operating profit/(loss) represents the sum of (i) earnings/(losses) of subsidiaries before interest income, interest expenses and income tax expenses; (ii) interest income; (iii) our equity in earnings of equity investees; and (iv) unallocated costs attributed to expenses incurred by our corporate head office. See note 25 to our consolidated financial statements in this annual report for additional information.

## **Taxation**

# Cayman Islands

Hutchison China MediTech Limited is incorporated in the Cayman Islands. The Cayman Islands currently levies no taxes on profits, income, gains or appreciation earned by individuals or corporations. In addition, our payment of dividends, if any, is not subject to withholding tax in the Cayman Islands. For more information, see Item 10.E. "Taxation—Overview of Tax Implications of Various Other Jurisdictions—Cayman Islands Taxation."

## People's Republic of China

Our subsidiaries and joint ventures incorporated in the PRC are governed by the PRC EIT Law and regulations. Under the EIT Law, the standard EIT rate is 25% on taxable profits as reduced by available tax losses. Tax losses may be carried forward to offset any taxable profits for the following five years. Our subsidiary, Hutchison MediPharma, was granted the TASE status from January 1, 2010 to December 31, 2018, and has been successful in its application to renew its HNTE status from January 1, 2017 to December 31, 2019; whereas our non-consolidated joint ventures, Hutchison Baiyunshan and Shanghai Hutchison Pharmaceuticals, have been successful in their respective applications to renew their HNTE status from January 1, 2017 to December 31, 2019. Accordingly, these entities were subject to a preferential EIT rate of 15% for the years ended December 31, 2015, 2016 and 2017.

For more information, see Item 10.E. "Taxation—Taxation in the PRC." Please also see Item. 3 "Key Information—Risk Factors—Our business benefits from certain PRC government tax incentives. The expiration of, changes to, or our PRC subsidiaries/joint ventures failing to continuously meet the criteria for these incentives could have a material adverse effect on our operating results by significantly increasing our tax expenses."

## Hong Kong

Hutchison China MediTech Limited and certain subsidiaries which have registered a branch in Hong Kong and are Hong Kong tax residents, as well as our subsidiaries incorporated in Hong Kong, are governed by applicable Hong Kong income tax laws and regulations. As such, they are subject to Hong Kong Profits Tax at the rate of 16.5% on their assessable profits as reduced by available tax losses for the years ended December 31, 2015, 2016 and 2017.

According to the EIT Law, dividends declared after January 1, 2008 and paid by PRC foreign-invested enterprises to their non-PRC parent companies will be subject to PRC withholding tax at 10% unless there is a tax treaty between the PRC and the jurisdiction in which the overseas parent company is a tax resident and which specifically exempts or reduces such withholding tax, and such tax exemption or reduction is approved by the relevant PRC tax authorities. Pursuant to the Arrangement, if the shareholder of the PRC enterprise is a Hong Kong tax resident and directly holds a 25% or more equity interest in the PRC enterprise and is considered to be the beneficial owner of dividends paid by the PRC enterprise, such withholding tax rate may be lowered to 5%, subject to approvals by the relevant PRC tax authorities. For more information, see Item 10.E. "Taxation—Taxation in the PRC" and "Taxation—Hong Kong Taxation."

# **Results of Operations**

The following table sets forth a summary of our consolidated results of operations for the years indicated. This information should be read together with our consolidated financial statements and related notes included elsewhere in this annual report. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

			Year Ended Do	ecember 31,		
	2017		2016		2015	
	\$'000	%	\$'000	%	\$'000	%
Revenues	241,203	100.0	216,080	100.0	178,203	100.0
Cost of sales	(175,820)	(72.9)	(156,328)	(72.4)	(110,777)	(62.2)
Research and development expenses	(75,523)	(31.3)	(66,871)	(31.0)	(47,368)	(26.6)
Selling expenses	(19,322)	(8.0)	(17,998)	(8.3)	(10,209)	(5.7)
Administrative expenses	(23,955)	(9.9)	(21,580)	(10.0)	(19,620)	(11.0)
Total other expense	(119)	(0.0)	(659)	(0.3)	(769)	(0.4)
Income tax expense	(3,080)	(1.3)	(4,331)	(2.0)	(1,605)	(0.9)
Equity in earnings of equity						
investees, net of tax	33,653	13.9	66,244	30.7	22,572	12.7
Net (loss)/income	(22,963)	(9.5)	14,557	6.7	10,427	5.9
Net (loss)/income attributable to our company	(26,737)	(11.1)	11,698	5.4	7,993	4.5
our company	<u>(20,737)</u>	(11.1)		J.4		4.5

# Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

## Revenues

Our revenues increased by 11.6% from \$216.1 million for the year ended December 31, 2016 to \$241.2 million for the year ended December 31, 2017.

This increase was driven by a \$24.4 million increase in revenue for the year ended December 31, 2017 from our Commercial Platform, representing a 13.5% increase from the revenue of \$180.9 million for the year ended December 31, 2016. The consolidated revenue from our Prescription Drugs business increased by \$16.6 million from \$149.8 million for the year ended December 31, 2016 to \$166.4 million for the year ended December 31, 2017. The increase was primarily attributable to the growth in our third-party drug distribution business. The consolidated revenue from our Consumer Health business also increased by \$7.8 million from \$31.0 million for the year ended December 31, 2016 to \$38.8 million for the year ended December 31, 2017. The increase was primarily attributable to higher levels of infant nutrition products and personal care products sold in 2017. The consolidated revenue from our Innovation Platform increased slightly by \$0.8 million from \$35.2 million for the year ended December 31, 2016 to \$36.0 million for the year ended December 31, 2017. The increase was attributable to a higher level of service fees that we received from our joint ventures.

Our Commercial Platform's results of operations are affected by seasonality. For more information, see "—Factors Affecting our Results of Operations—Commercial Platform—Seasonality."

# Cost of Sales

Our cost of sales increased by 12.5% from \$156.3 million for the year ended December 31, 2016 to \$175.8 million for the year ended December 31, 2017. This increase was primarily driven by a \$15.4 million increase in cost of sales from Hutchison Sinopharm under our Prescription Drugs business, as well as a \$4.0 million increase in cost of sales from Hutchison Hain Organic under our Consumer Health business. Cost of sales as a percentage of our revenue from our Commercial Platform decreased from 86.4% to

85.7% across these periods, primarily due to product mix resulting in an increased proportion of sales of higher margin products.

# Research and Development Expenses

Our research and development expenses increased by 12.9% from \$66.9 million for the year ended December 31, 2016 to \$75.5 million for the year ended December 31, 2017, which was primarily attributable to a \$5.5 million increase in payments to CROs and other clinical trial related costs and a \$3.1 million increase in employee compensation related costs. These increased costs incurred by our Innovation Platform was due to a significant expansion of clinical activities and rapid organization growth to support these clinical activities. The number of ongoing clinical studies for our drug candidates increased from studies in 30 target patient populations as of December 31, 2016 to studies in 36 target patient populations as of December 31, 2017. In particular, this increase was attributable to the expansion of the savolitinib and fruquintinib development programs. As a result, research and development expenses as a percentage of our total revenue increased from 31.0% in the year ended December 31, 2016 to 31.3% in the year ended December 31, 2017.

## Selling Expenses

Our selling expenses increased by 7.4% from \$18.0 million for the year ended December 31, 2016 to \$19.3 million for the year ended December 31, 2017. This increase was primarily driven by a \$0.9 million increase in selling expenses under our Consumer Health business and a \$0.4 million increase in selling expenses under our Prescription Drugs business. Selling expenses as a percentage of our revenue from our Commercial Platform decreased from 10.0% to 9.4% across these periods, primarily due to increased sales by our third-party Prescription Drug distribution and Consumer Health businesses.

## Administrative Expenses

Our administrative expenses increased by 11.0% from \$21.6 million for the year ended December 31, 2016 to \$24.0 million for the year ended December 31, 2017. This increase was primarily due to a \$1.2 million and \$0.9 million increase in administrative expenses incurred by our Innovation Platform and corporate head office, mainly related to the increased staff cost, office expenses and organization and third-party advisor costs as a result of operating as a U.S. public company for a full calendar year. Administrative expenses had remained relatively stable as a percentage of our total revenue.

## Other Expenses

Total other expenses decreased from \$0.7 million for the year ended December 31, 2016 to \$0.1 million for the year ended December 31, 2017, primarily due to higher interest income offset by higher foreign currency translation loss.

Our interest income increased from \$0.5 million for the year ended December 31, 2016 to \$1.2 million for the year ended December 31, 2017. The increase was attributable to a higher level of bank deposits after receiving proceeds from our follow-on offering in October 2017. Our interest expense decreased slightly from \$1.6 million for the year ended December 31, 2016 to \$1.5 million for the year ended December 31, 2017. These interest expenses primarily comprised interest and guarantee fee payments on bank loans in 2016 and 2017.

# Income Tax Expense

Our income tax expense decreased by 28.9% from \$4.3 million for the year ended December 31, 2016 to \$3.1 million for the year ended December 31, 2017 due to a decrease in withholding taxes accrued on the net income from our Commercial Platform businesses for the year ended December 31, 2017. The higher withholding tax accrued for the year ended December 31, 2016 was due to equity in earnings of

Shanghai Hutchison Pharmaceuticals including a one-time gain of \$40.4 million relating to land compensation and other government subsidies.

# Equity in Earnings of Equity Investees

Our equity in earnings of equity investees, net of tax, decreased by 49.2% from \$66.2 million for the year ended December 31, 2016 to \$33.7 million for the year ended December 31, 2017. This decrease was primarily due to a decrease in net income at our Commercial Platform's non-consolidated joint ventures as well as an increase in net loss at Nutrition Science Partners, our Innovation Platform's non-consolidated joint venture. Our equity in earnings of Shanghai Hutchison Pharmaceuticals included one-time gains, net of tax, of \$40.4 million from land compensation and other government subsidies in the year ended December 31, 2016 and \$2.5 million from government subsidies in the year ended December 31, 2017 in each case paid to Shanghai Hutchison Pharmaceuticals by the Shanghai government.

# Shanghai Hutchison Pharmaceuticals

The following table shows a summary of the results of operations of Shanghai Hutchison Pharmaceuticals for the years indicated. The consolidated financial statements of Shanghai Hutchison Pharmaceuticals are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report.

	Year Ended December 31,					
	2017	,	2016	16		
	(\$'000)	%	(\$'000)	%		
Revenue	244,557	100.0	222,368	100.0		
Cost of sales	(68,592)	(28.0)	(64,237)	(28.9)		
Selling expenses	(104,504)	(42.7)	(92,487)	(41.6)		
Administrative expenses	(13,257)	(5.4)	(13,278)	(6.0)		
Gain on disposal of assets held for sale	<u>—</u>	_	88,536	39.8		
Taxation charge	(10,874)	(4.4)	(27,645)	(12.4)		
Profit for the year	55,623	22.7	120,499	54.2		
Equity in earnings of equity investee attributable to our company	27,812	11.4	60,250	27.1		

Shanghai Hutchison Pharmaceuticals' revenue increased by 10.0% from \$222.4 million for the year ended December 31, 2016 to \$244.6 million for the year ended December 31, 2017, which was primarily due to increased sales of She Xiang Bao Xin pills, a vasodilator used in the treatment of heart conditions. Sales of She Xiang Bao Xin pills grew by 7.1% from \$195.4 million for the year ended December 31, 2016 to \$209.2 million for the year ended December 31, 2017, primarily due to continued price increases and geographical expansion of sales coverage.

Cost of sales increased by 6.8% from \$64.2 million for the year ended December 31, 2016 to \$68.6 million for the year ended December 31, 2017, primarily due to increased cost of goods sold as a result of increased sales of She Xiang Bao Xin pills.

Selling expenses during these periods increased by 13.0% from \$92.5 million for the year ended December 31, 2016 to \$104.5 million for the year ended December 31, 2017 as a result of increased spending on marketing and promotional activities to support the increase in sales.

Administrative expenses remained relatively stable at \$13.3 million for the years ended December 31, 2016 and 2017.

Taxation charge decreased by 60.7% from \$27.6 million for the year ended December 31, 2016 to \$10.9 million for the year ended December 31, 2017, which was primarily due to the decrease in profit before taxation between these periods.

As a result of the foregoing and the one-time gain of \$40.4 million from land compensation and other government subsidies received from the Shanghai government in 2016 which did not occur in 2017, profit decreased by 53.8% from \$120.5 million for the year ended December 31, 2016 to \$55.6 million for the year ended December 31, 2017. Our equity in earnings of equity investees contributed by this joint venture was \$60.3 million and \$27.8 million for the years ended December 31, 2016 and 2017, respectively.

# Hutchison Baiyunshan

The following table shows a summary of the results of operations of Hutchison Baiyunshan for the years indicated. The consolidated financial statements of Hutchison Baiyunshan are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report.

	Year Ended December 31,				
	2017		201	16	
	(\$'000)	%	(\$'000)	%	
Revenue	227,422	100.0	224,131	100.0	
Cost of sales	(135,964)	(59.8)	(134,776)	(60.1)	
Selling expenses	(45,262)	(19.9)	(46,873)	(20.9)	
Administrative expenses	(24,541)	(10.8)	(21,716)	(9.7)	
Taxation charge	(3,629)	(1.6)	(3,631)	(1.6)	
Profit attributable to equity holders of Hutchison Baiyunshan	20,776	9.1	20,376	9.1	
Equity in earnings of equity investee attributable to our company	10,388	4.6	10,188	4.5	

Hutchison Baiyunshan's revenue increased slightly by 1.5% from \$224.1 million for the year ended December 31, 2016 to \$227.4 million for the year ended December 31, 2017, which was primarily due to increased sales of certain of its drug products.

Cost of sales increased by 0.9% from \$134.8 million for the year ended December 31, 2016 to \$136.0 million for the year ended December 31, 2017, primarily due to increased sales. The increase in cost of sales was smaller than the increase in revenues due to a change in product mix resulting in a higher proportion of sales of higher margin products.

Selling expenses during these periods decreased by 3.4% from \$46.9 million for the year ended December 31, 2016 to \$45.3 million for the year ended December 31, 2017 due to less sales and marketing activities.

Administrative expenses increased by 13.0% from \$21.7 million for the year ended December 31, 2016 to \$24.5 million for the year ended December 31, 2017 due to an increase in general overhead costs incurred.

Taxation charge remained relatively stable at \$3.6 million for the years ended December 31, 2016 and 2017 due to relatively stable profit before taxation across these periods.

As a result of the foregoing, profit attributable to equity holders of Hutchison Baiyunshan increased by 2.0% from \$20.4 million for the year ended December 31, 2016 to \$20.8 million for the year ended December 31, 2017. Our equity in earnings of equity investees contributed by this joint venture was \$10.2 million and \$10.4 million for the years ended December 31, 2016 and 2017, respectively.

#### Nutrition Science Partners

The following table shows a summary of the results of operations of Nutrition Science Partners for the years indicated. The consolidated financial statements of Nutrition Science Partners are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report.

	Year Ended December 31,				
	2017		2016		
	(\$'000)	%	(\$'000)	%	
Revenue	_	_	_	_	
Loss for the year	(9,210)	100.0	(8,482)	100.0	
Equity in earnings of equity investee attributable to our company	(4,605)	50.0	(4,241)	50.0	

Nutrition Science Partners had losses of \$8.5 million and \$9.2 million for the years ended December 31, 2016 and 2017, respectively. Nutrition Science Partners had no revenue during these periods. The increase in net loss across these periods was primarily attributable to higher expenditures on personnel costs related to the development of drug candidates from Nutrition Science Partners' botanical library. Our equity in earnings of equity investees contributed by this joint venture was losses of \$4.2 million and \$4.6 million for the years ended December 31, 2016 and 2017, respectively.

For more information on the financial results of our non-consolidated joint ventures, see "—Key Components of Results of Operations—Equity in Earnings of Equity Investees."

## Net (Loss)/Income

As a result of the foregoing, our net income decreased from a net income of \$14.6 million for the year ended December 31, 2016 to a net loss of \$23.0 million for the year ended December 31, 2017. Net income attributable to our company decreased from a net income of \$11.7 million for the year ended December 31, 2016 to a net loss of \$26.7 million for the year ended December 31, 2017.

# Operating Profit/(Loss)

Our operating profit decreased from an operating profit of \$20.5 million for the year ended December 31, 2016 to an operating loss of \$18.4 million for the year ended December 31, 2017 as a result of a significant decrease in operating profit of our Commercial Platform from \$74.3 million for the year ended December 31, 2016 to \$45.1 million for the year ended December 31, 2017 as well as an increase in operating loss of our Innovative Platform from \$40.8 million for the year ended December 31, 2016 to \$52.0 million for the year ended December 31, 2017. The decrease in operating profit of our Commercial Platform across these periods was primarily due to equity in earnings of Shanghai Hutchison Pharmaceuticals including a one-time gain of \$40.4 million relating to land compensation and other government subsidies in 2016 which did not occur in 2017. The increase in operating loss of our Innovation Platform was due to a significant expansion of clinical activities, rapid organization growth to support these clinical activities and investment in the expansion of small molecule manufacturing operations.

# Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

# Revenues

Our revenues increased by 21.3% from \$178.2 million for the year ended December 31, 2015 to \$216.1 million for the year ended December 31, 2016.

This increase was driven by a \$54.7 million increase in revenue for the year ended December 31, 2016 from our Commercial Platform, representing a 43.3% increase from the revenue of \$126.2 million for the year ended December 31, 2015. The increase was partially offset by a 32.3% decrease in revenue from our

Innovation Platform for the year ended December 31, 2016 to \$35.2 million from \$52.0 million in the year ended December 31, 2015. The growth in revenue from our Commercial Platform was driven by the inclusion of a full 12-month period of Seroquel sales in China for the year ended December 31, 2016, which our consolidated joint venture Hutchison Sinopharm began marketing under an exclusive license from AstraZeneca in the second quarter of 2015. The decrease in the revenue from our Innovation Platform for the year ended December 31, 2016 was attributable to a lower level of milestone payments, services fees and clinical cost reimbursements that we received from our collaboration partners including AstraZeneca and Eli Lilly.

The consolidated revenue from our Consumer Health business also increased by \$10.3 million from \$20.7 million for the year ended December 31, 2015 to \$31.0 million for the year ended December 31, 2016. The increase was primarily attributable to higher levels of infant nutrition products and personal care products sold in 2016.

Our Commercial Platform's results of operations are affected by seasonality. For more information, see "—Factors Affecting our Results of Operations—Commercial Platform—Seasonality."

# Cost of Sales

Our cost of sales increased by 41.1% from \$110.8 million for the year ended December 31, 2015 to \$156.3 million for the year ended December 31, 2016. This increase was primarily driven by a \$39.2 million increase in cost of sales from Hutchison Sinopharm under our Prescription Drugs business, as well as a \$4.0 million increase in cost of sales from Hutchison Hain Organic under our Consumer Health business. Cost of sales as a percentage of our revenue from our Commercial Platform decreased from 87.8% to 86.4% across these periods, primarily due to increased sales of Seroquel, which has a relatively higher margin than the other products sold by our Commercial Platform.

# Research and Development Expenses

Our research and development expenses increased by 41.2% from \$47.4 million for the year ended December 31, 2015 to \$66.9 million for the year ended December 31, 2016, which was primarily attributable to a \$15.1 million increase in payments to CROs and other clinical trial related costs and a \$4.4 million increase in employee compensation related costs. These increased costs incurred by our Innovation Platform was due to a significant expansion of clinical activities and rapid organization growth to support these clinical activities. The number of ongoing clinical studies for our drug candidates increased from 19 studies as of December 31, 2015 to 30 studies as of December 31, 2016. In particular, this increase was attributable to our share of the cost of the savolitinib development program as well as the increased cost associated with the expansion of the sulfatinib and HMPL-523 development programs. As a result, research and development expenses as a percentage of our total revenue increased from 26.6% in the year ended December 31, 2016.

# Selling Expenses

Our selling expenses increased by 76.3% from \$10.2 million for the year ended December 31, 2015 to \$18.0 million for the year ended December 31, 2016. This increase was primarily driven by a \$4.8 million increase in selling expenses under our Consumer Health business and a \$3.0 million increase in selling expenses under our Prescription Drugs business. Selling expenses as a percentage of our revenue from our Commercial Platform increased from 8.1% to 10.0% across these periods, primarily due to increased selling expenses incurred by Hutchison Sinopharm for expanding its third-party distribution and commercialization business as well as increased marketing expenses related to the development of the Zhi Ling Tong infant nutrition business after Hutchison Sinopharm took over such business from a third-party distributor.

## Administrative Expenses

Our administrative expenses increased by 10.0% from \$19.6 million for the year ended December 31, 2015 to \$21.6 million for the year ended December 31, 2016. This increase was primarily due to a \$2.2 million increase in administrative expenses incurred by our corporate head office, mainly related to the increased organization and third-party advisor costs as a result of us becoming a U.S. public company in March 2016. Administrative expenses as a percentage of our total revenue decreased from 11.0% to 10.0% across these periods, primarily due to the increase in revenue from our Hutchison Sinopharm business, which has relatively lower administrative expenses in proportion to revenue compared to our other businesses, partially offset by the increased administrative expenses at our corporate head office.

# Other Expenses

Total other expenses decreased from \$0.8 million for the year ended December 31, 2015 to \$0.7 million for the year ended December 31, 2016, primarily due to an increase in other income resulting from payments to us by the depositary bank which administers our ADS program in 2016.

Our interest expense increased from \$1.4 million for the year ended December 31, 2015 to \$1.6 million for the year ended December 31, 2016, while our interest income remained relatively stable at \$0.5 million for the years ended December 31, 2015 and 2016. These interest expenses primarily comprised interest and guarantee fee payments on bank loans in 2015 and 2016.

# Income Tax Expense

Our income tax expense increased by 169.8% from \$1.6 million for the year ended December 31, 2015 to \$4.3 million for the year ended December 31, 2016 due to the increase in the net income of our Commercial Platform businesses and the 5% withholding taxes accrued on the net income from our Commercial Platform businesses for the year ended December 31, 2016.

# Equity in Earnings of Equity Investees

Our equity in earnings of equity investees (net of tax) increased by 193.5% from \$22.6 million for the year ended December 31, 2015 to \$66.2 million for the year ended December 31, 2016. This increase was primarily due to an increase in net income at our Commercial Platform's non-consolidated joint ventures, Shanghai Hutchison Pharmaceuticals and Hutchison Baiyunshan, including a one-time gain of \$40.4 million, net of tax, relating to land compensation and other subsidies paid to Shanghai Hutchison Pharmaceuticals by the Shanghai government and an increase in net loss at Nutrition Science Partners, our Innovation Platform's non-consolidated joint venture.

## Shanghai Hutchison Pharmaceuticals

The following table shows a summary of the results of operations of Shanghai Hutchison Pharmaceuticals for the years indicated. The consolidated financial statements of Shanghai Hutchison Pharmaceuticals are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report.

	Year Ended December 31,				
	201	6	201:	5	
	(\$'000)	%	(\$'000)	%	
Revenue	222,368	100.0	181,140	100.0	
Cost of sales	(64,237)	(28.9)	(53,532)	(29.6)	
Selling expenses	(92,487)	(41.6)	(78,429)	(43.3)	
Administrative expenses	(13,278)	(6.0)	(12,317)	(6.8)	
Gain on disposal of assets held for sale	88,536	39.8		_	
Taxation charge	(27,645)	(12.4)	(6,094)	(3.4)	
Profit for the year	120,499	54.2	31,307	17.3	
Equity in earnings of equity investee attributable to our company	60,250	27.1	15,654	8.6	

Shanghai Hutchison Pharmaceuticals' revenue increased by 22.8% from \$181.1 million for the year ended December 31, 2015 to \$222.4 million for the year ended December 31, 2016, which was primarily due to increased sales of She Xiang Bao Xin pills, a vasodilator used in the treatment of heart conditions. Sales of She Xiang Bao Xin pills grew by 22.6% from \$159.3 million for the year ended December 31, 2015 to \$195.4 million for the year ended December 31, 2016, primarily due to continued geographical expansion of sales coverage.

Cost of sales increased by 20.0% from \$53.5 million for the year ended December 31, 2015 to \$64.2 million for the year ended December 31, 2016, primarily due to increased cost of goods sold as a result of increased sales of She Xiang Bao Xin pills.

Selling expenses during these periods increased by 17.9% from \$78.4 million for the year ended December 31, 2015 to \$92.5 million for the year ended December 31, 2016 as a result of increased spending on marketing and promotional activities to support the increase in sales.

Administrative expenses increased by 7.8% from \$12.3 million for the year ended December 31, 2015 to \$13.3 million for the year ended December 31, 2016, primarily as a result of compensation expenses due to salary increases.

Taxation charge increased by 353.6% from \$6.1 million for the year ended December 31, 2015 to \$27.6 million for the year ended December 31, 2016, which was primarily due to the increase in profit before taxation between these periods.

As a result of the foregoing and the one-time gain on disposal of assets held for sale of \$88.5 million related to land compensation received from the Shanghai government, profit increased by 284.9% from \$31.3 million for the year ended December 31, 2015 to \$120.5 million for the year ended December 31, 2016. Our equity in earnings of equity investees contributed by this joint venture was \$15.7 million and \$60.3 million for the years ended December 31, 2015 and 2016, respectively.

## Hutchison Baiyunshan

The following table shows a summary of the results of operations of Hutchison Baiyunshan for the years indicated. The consolidated financial statements of Hutchison Baiyunshan are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report.

	Year Ended December 31,				
	2016		201	5	
	(\$'000)	%	(\$'000)	%	
Revenue	224,131	100.0	211,603	100.0	
Cost of sales	(134,776)	(60.1)	(120,142)	(56.8)	
Selling expenses	(46,873)	(20.9)	(45,325)	(21.4)	
Administrative expenses	(21,716)	(9.7)	(23,722)	(11.2)	
Taxation charge	(3,631)	(1.6)	(3,948)	(1.9)	
Profit attributable to equity holders of Hutchison Baiyunshan	20,376	9.1	21,376	10.1	
Equity in earnings of equity investee attributable to our company	10,188	4.5	10,688	5.1	

Hutchison Baiyunshan's revenue increased by 5.9% from \$211.6 million for the year ended December 31, 2015 to \$224.1 million for the year ended December 31, 2016, which was primarily due to increased sales of certain of its drug products, for which revenue increased by 7.8% from \$144.5 million for the year ended December 31, 2015 to \$155.8 million for the year ended December 31, 2016.

Cost of sales increased by 12.2% from \$120.1 million for the year ended December 31, 2015 to \$134.8 million for the year ended December 31, 2016, primarily due to increased sales. The increase in cost of sales was larger than the increase in revenues due to a change in product mix resulting in a higher proportion of sales of lower margin products.

Selling expenses during these periods increased by 3.4% from \$45.3 million for the year ended December 31, 2015 to \$46.9 million for the year ended December 31, 2016 to support the growth in sales across these periods.

Administrative expenses decreased from \$23.7 million for the year ended December 31, 2015 to \$21.7 million for the year ended December 31, 2016 due to a decrease in general overhead costs incurred.

Taxation charge decreased from \$3.9 million for the year ended December 31, 2015 to \$3.6 million for the year ended December 31, 2016 due to decreased profit before taxation across these periods.

As a result of the foregoing, profit attributable to equity holders of Hutchison Baiyunshan decreased by 4.7% from \$21.4 million for the year ended December 31, 2015 to \$20.4 million for the year ended December 31, 2016. Our equity in earnings of equity investees contributed by this joint venture was \$10.7 million and \$10.2 million for the years ended December 31, 2015 and 2016, respectively.

## Nutrition Science Partners

The following table shows a summary of the results of operations of Nutrition Science Partners for the years indicated. The consolidated financial statements of Nutrition Science Partners are prepared in accordance with IFRS as issued by the IASB and are presented separately elsewhere in this annual report.

	Year Ended December 31,				
	2016		2015		
	(\$'000)	%	(\$'000)	%	
Revenue	_	_	_	_	
Loss for the year	(8,482)	100.0	(7,552)	100.0	
Equity in earnings of equity investee attributable to our company	(4,241)	50.0	(3,776)	50.0	

Nutrition Science Partners had losses of \$7.6 million and \$8.5 million for the years ended December 31, 2015 and 2016, respectively. Nutrition Science Partners had no revenue during these periods. The increase in net loss across these periods was primarily attributable to higher expenditures on personnel costs related to the development of drug candidates from Nutrition Science Partners' botanical library. Our equity in earnings of equity investees contributed by this joint venture was losses of \$3.8 million and \$4.2 million for the years ended December 31, 2015 and 2016, respectively.

For more information on the financial results of our non-consolidated joint ventures, see "—Key Components of Results of Operations—Equity in Earnings of Equity Investees."

#### Net Income

As a result of the foregoing, our net income improved from a net income of \$10.4 million for the year ended December 31, 2015 to a net income of \$14.6 million for the year ended December 31, 2016. Net income attributable to our company improved from a net income of \$8.0 million for the year ended December 31, 2015 to a net income of \$11.7 million for the year ended December 31, 2016.

# **Operating Profit**

Our operating profit increased by 52.7% from \$13.4 million for the year ended December 31, 2015 to \$20.5 million for the year ended December 31, 2016 as a result of a significant increase in operating profit of our Commercial Platform from \$28.2 million for the year ended December 31, 2015 to \$74.3 million for the year ended December 31, 2016, partially offset by an increase in operating loss of our Innovative Platform from \$3.8 million for the year ended December 31, 2015 to \$40.8 million for the year ended December 31, 2016. The increase in operating profit of our Commercial Platform across these periods was attributable to an increase in equity in earnings of Shanghai Hutchison Pharmaceuticals of \$44.6 million from \$15.7 million for the year ended December 31, 2015 to \$60.3 million for the year ended December 31, 2016. The increase in operating loss of our Innovation Platform was due to a significant expansion of clinical activities, rapid organization growth to support these clinical activities and a decrease in revenue from license and collaboration agreements due to timing of milestone achievements.

# B. Liquidity and Capital Resources

To date, we have taken a multi-source approach to funding through cash flows generated from and dividend payments from our Commercial Platform, service and milestone and upfront payments from our Innovation Platform's collaboration partners, and bank borrowings. We have also received various financial support from Hutchison Whampoa Limited, an affiliate of our majority shareholder, in the form of guarantees and undertakings for bank borrowings as well as investments from other parties since our founding, proceeds from our listings on the AIM market of the London Stock Exchange in 2006 and the Nasdaq Global Select Market in 2016 and follow-on offering in 2017.

Our Innovation Platform has historically not generated significant profits or has operated at a net loss, as creating potential global first-in-class or best-in-class drug candidates requires a significant investment of resources over a prolonged period of time. As a result, we anticipate that we may need additional financing for our Innovation Platform in future periods. See Item 3.D. "Risk Factors—Risks Related to Our Innovation Platform—Historically, our Innovation Platform has not generated significant profits or has operated at a net loss."

As of December 31, 2017, we had cash and cash equivalents and short-term investments of \$358.3 million and unutilized bank facilities of \$121.3 million. Substantially all of our bank deposits are at major financial institutions, which we believe are of high credit quality. As of December 31, 2017, we had \$30.0 million in bank loans, including (i) a \$20.0 million term loan from Bank of America N.A. and a \$10.0 million term loan from Deutsche Bank AG, Hong Kong Branch, both of which will expire in August 2018. Our total weighted average cost of bank borrowings, including all interest and guarantee fees payable

with respect to our prior loan with Scotiabank, was 2.7% as of December 31, 2017. In February 2017, we entered into new credit facility agreements with each of Bank of America N.A. and Deutsche Bank AG, Hong Kong Branch of \$45.0 million and \$25.0 million, respectively, which replaced the previous combined \$60.0 million credit facility agreement we had entered into with these two banks in February 2016. In November 2017, we entered into a new credit facility agreement with Scotiabank for the provision of unsecured credit facilities in the aggregate amount of \$51.3 million. The credit facility includes (i) a \$26.9 million 3-year term loan facility; and (ii) a \$24.4 million 18-month revolving loan facility, which replaced the previous four-year Scotiabank loan entered in December 2011 and subsequently renewed in June 2014.

Certain of our subsidiaries and non-consolidated joint ventures, including those registered as wholly foreign-owned enterprises in China, are required to set aside at least 10.0% of their after-tax profits to their general reserves until such reserves reach 50.0% of their registered capital. There is no fixed percentage of after-tax profit required to set aside for the general reserves for our PRC joint ventures. Profit appropriated to the reserve funds for our subsidiaries and non-consolidated joint ventures incorporated in the PRC was approximately \$24,000, \$15,000 and \$10,000 for the years ended December 31, 2015, 2016 and 2017, respectively. In addition, as a result of PRC regulations restricting dividend distributions from such reserve funds and from a company's registered capital, our PRC subsidiaries are restricted in their ability to transfer a certain amount of their net assets to us as cash dividends, loans or advances. This restricted portion amounted to \$7.3 million as of December 31, 2017. Although we do not currently require any such dividends, loans or advances from our PRC subsidiaries to fund our operations, should we require additional sources of liquidity in the future, such restrictions may have a material adverse effect on our liquidity and capital resources. For more information, see Item 4.B. "Business Overview—Regulation—PRC Regulation of Foreign Currency Exchange, Offshore Investment and State-Owned Assets—Regulation on Dividend Distribution."

In addition, our non-consolidated joint ventures held an aggregate of \$67.0 million in cash and cash equivalents and bank deposits maturing over three months and no bank borrowings as of December 31, 2017. These cash and cash equivalents are only accessible by us through dividend payments from these joint ventures. The level of dividends declared by these joint ventures is subject to agreement each year between us and our joint venture partners based on the profitability and working capital needs of the joint ventures. As a result, we cannot guarantee that these joint ventures will continue to pay dividends to us in the future at the same rate we have enjoyed in the past, or at all, which may have a material adverse effect on our liquidity and capital resources. As of December 31, 2017, our Innovation Platform joint venture, Nutrition Science Partners, has not paid any dividends. For more information, see Item 3.D. "Risk Factors—Risks Related to Our Commercial Platform—As a significant portion of our Commercial Platform business is conducted through joint ventures, we are largely dependent on the success of our joint ventures and our receipt of dividends or other payments from our joint ventures for cash to fund our operations."

We believe that our current levels of cash and cash equivalents, short-term investments, along with cash flows from operations, dividend payments and bank borrowings, will be sufficient to meet our anticipated cash needs for at least the next 12 months. However, we may require additional financing in order to fund all of the clinical development efforts at our Innovation Platform that we plan to undertake

to accelerate the development of our clinical-stage drug candidates. For more information, see Item 3.D. "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital."

	Year E	Year Ended December 31,				
	2017	2016	2015			
		(\$'000)				
Cash Flow Data:						
Net cash used in operating activities	(8,943)	(9,569)	(9,385)			
Net cash (used in)/generated from investing activities	(260,780)	(33,597)	8,855			
Net cash generated from/(used in) financing activities	273,196	92,435	(5,471)			
Net increase/(decrease) in cash and cash equivalents	3,473	49,269	(6,001)			
Effect of exchange rate changes	2,361	(1,779)	(1,004)			
Cash and cash equivalents at beginning of the year	79,431	31,941	38,946			
Cash and cash equivalents at end of the year	85,265	79,431	31,941			

# Net Cash used in Operating Activities

Net cash used in operating activities was \$9.6 million for the year ended December 31, 2016 compared to net cash used in operating activities of \$8.9 million for the year ended December 31, 2017. The net change was primarily attributable to a \$25.1 million increase in dividends received from our equity investees from \$30.5 million for the year ended December 31, 2016 to \$55.6 million for the year ended December 31, 2017 which was the result of increased revenue and funds available from land compensation paid to our equity investees in 2016. This increase was partially offset by an increase in research and development spending in our Innovation Platform as well as the effects of changes in working capital, namely an aggregate decrease of \$14.5 million in the year ended December 31, 2017 primarily due to delayed payments from 2016 which were settled in 2017, as compared to an aggregate increase of \$3.4 million in the year ended December 31, 2016.

Net cash used in operating activities was \$9.4 million for the year ended December 31, 2015 compared to net cash used in operating activities of \$9.6 million for the year ended December 31, 2016. The net change was primarily attributable to a \$24.1 million increase in dividends received from our equity investees from \$6.4 million for the year ended December 31, 2015 to \$30.5 million for the year ended December 31, 2016 resulting from increased revenue and gain from land compensation paid to our equity investees and the effects of changes in working capital due to an increase of \$19.0 million in accounts payable and other payables, accruals and advance receipts due to delays in payments to suppliers in the year ended December 31, 2016, as compared to an increase of \$8.3 million in the year ended December 31, 2015, offset by increases in research and development spending in our Innovation Platform.

# Net Cash (used in)/generated from Investing Activities

Net cash used in investing activities was \$33.6 million for the year ended December 31, 2016, compared to net cash used in investing activities of \$260.8 million for the year ended December 31, 2017. This change was primarily attributable to net deposits in short-term investments of \$248.8 million for the year ended December 31, 2017 compared to \$24.3 million for the year ended December 31, 2016. This change was also attributable to an additional \$7.0 million share capital contribution to Nutrition Science Partners in 2017 compared to \$5.0 million in 2016.

Net cash generated from investing activities was \$8.9 million for the year ended December 31, 2015, compared to net cash used in investing activities of \$33.6 million for the year ended December 31, 2016. This change was primarily attributable to net deposits in short-term investments of \$24.3 million for the year ended December 31, 2016 compared to a net withdrawal of deposits in short-term investments of

\$12.2 million for the year ended December 31, 2015. This change was also attributable to an additional \$5.0 million share capital contribution to Nutrition Science Partners in 2016 by us.

# Net Cash generated from/(used in) Financing Activities

Net cash generated from financing activities was \$92.4 million for the year ended December 31, 2016, compared to net cash generated from financing activities of \$273.2 million for the year ended December 31, 2017. This change was primarily attributable to net proceeds of \$292.7 million from the issuance of ordinary shares in the form of ADS upon our follow-on offering in the United States in October 2017 as compared to net proceeds of \$97.3 million from the issuance of ordinary shares in the form of ADS upon our initial public offering in the United States in 2016. The change was also attributable to a net decrease in bank borrowings of \$16.9 million for the year ended December 31, 2017 as compared to a net decrease of \$3.1 million for the year ended December 31, 2016.

Net cash used in financing activities was \$5.5 million for the year ended December 31, 2015, compared to net cash generated from financing activities of \$92.4 million for the year ended December 31, 2016. This change was primarily attributable to net proceeds of \$97.3 million from the issuance of ordinary shares in the form of ADS upon our initial public offering in the United States in 2016.

## Loan Facilities

In November 2015, we renewed a three-year revolving loan facility with HSBC with an annual interest rate of 1.25% over the Hong Kong Inter-bank Offered Rate, or HIBOR. This facility will expire in November 2018. The credit limit of this loan is HK\$234.0 million (\$30.0 million). In February 2017, \$2.5 million was drawn from this facility, and the amount was fully repaid in March 2017. As of December 31, 2017, there were no amounts due under this loan. The proceeds from previous drawdowns of this loan facility were used for working capital purposes prior to repayment. Interest expenses accrued and paid for this loan were approximately \$295,000, \$243,000 and \$3,000 for the years ended December 31, 2015, 2016 and 2017, respectively.

In February 2016, our Hong Kong subsidiary, Hutchison China MediTech (HK) Limited, entered into a facility agreement with Bank of America N.A. and Deutsche Bank AG, Hong Kong Branch for the provision of unsecured credit facilities in the aggregate amount of HK\$468.0 million (\$60.0 million). These credit facilities included (i) a HK\$156.0 million (\$20.0 million) term loan facility with a term of 18 months and an annual interest rate of 1.35% over HIBOR; and (ii) a HK\$312.0 million (\$40.0 million) revolving loan facility with a term of 12 months and an annual interest rate of 1.30% over HIBOR. In March 2017, the term loan facility of HK\$156.0 million (\$20.0 million) as part of the unsecured credit facilities was fully repaid and the unsecured credit facilities were terminated.

In February 2017, our subsidiary Hutchison China MediTech (HK) Limited entered into new credit facility agreements with each of Bank of America N.A. and Deutsche Bank AG, Hong Kong Branch for the provision of unsecured credit facilities in the aggregate amount of HK\$546.0 million (\$70.0 million). The credit facility with Bank of America N.A. includes (i) a HK\$156.0 million (\$20.0 million) term loan facility and (ii) a HK\$195.0 million (\$25.0 million) revolving loan facility, both with a term of 18 months and an annual interest rate of 1.25% over HIBOR. The term loan was drawn from this credit facility in March 2017 and is due in August 2018. The credit facility with Deutsche Bank AG, Hong Kong Branch includes (i) a HK\$78.0 million (\$10.0 million) term loan facility and (ii) a HK\$117.0 million (\$15.0 million) revolving loan facility, both with a term of 18 months and an annual interest rate of 1.25% over HIBOR. The term loan was drawn from this credit facility in August 2017 and is due in August 2018. The two new credit facility agreements replaced the previous credit facility agreement with these two banks. As of December 31, 2017, no amounts were drawn from the revolving loan facilities and HK\$156.0 million (\$20.0 million) and HK\$78.0 million (\$10.0 million) was outstanding on the term loan facilities,

respectively. These credit facilities are guaranteed by Chi-Med and include certain financial covenant requirements.

In November 2017, our subsidiary Hutchison China MediTech Finance Holdings Limited entered into a HK\$210.0 million (\$26.9 million) three-year term loan and HK\$190.0 million (\$24.4 million) 18-month revolving loan facility with Scotiabank. The new term loan facility bears an annual interest rate of 1.50% over HIBOR and the new revolving loan facility bears an annual interest rate of 1.25% over HIBOR. The new term loan and revolving loan facility will expire in November 2020 and May 2019, respectively. As of December 31, 2017, no amounts have been drawn from the term loan or the revolving loan facilities. Our previous four-year term loan with Scotiabank entered in June 2014 was fully repaid in November 2017. The previous term loan was guaranteed by Hutchison Whampoa Limited for an annual guarantee fee of 1.75%. Interest expenses accrued and paid for this loan were \$0.4 million, \$0.4 million and \$0.3 million for the years ended December 31, 2015, 2016 and 2017, respectively. Guarantee fees accrued and paid for these loans with Scotiabank were \$0.5 million, \$0.5 million and \$0.3 million for the years ended December 31, 2015, 2016 and 2017, respectively.

In addition, our non-consolidated joint ventures Shanghai Hutchison Pharmaceuticals, Hutchison Baiyunshan and Nutrition Science partners had no bank borrowings outstanding as of December 31, 2017.

# Capital Expenditures

We had capital expenditures of \$3.3 million, \$4.3 million and \$5.0 million for the years ended December 31, 2015, 2016 and 2017, respectively. Our capital expenditures during these periods were primarily used for the purchases of property, plant and equipment to expand the Hutchison MediPharma research facilities and the new manufacturing facility in Suzhou, China, which produces Phase III clinical supplies and will be used to produce fruquintinib and other drug candidates. Our capital expenditures have been primarily funded by cash flows from operations and financing from bank borrowings.

As of December 31, 2017, we had commitments for capital expenditures of approximately \$0.2 million, primarily for purchases of property, plant and equipment to expand the Hutchison MediPharma research facilities and the new Suzhou manufacturing facility. We expect to fund these capital expenditures through cash flows from operations and financing from bank borrowings.

Our non-consolidated joint venture Shanghai Hutchison Pharmaceuticals had capital expenditures (net of government subsidies) of \$42.1 million, \$11.0 million and \$6.2 million for the years ended December 31, 2015, 2016 and 2017, respectively. These capital expenditures were primarily related to the construction of the new production facilities in Feng Pu district in Shanghai. These capital expenditures were primarily funded through cash flows from operations of Shanghai Hutchison Pharmaceuticals and bank borrowings.

Our non-consolidated joint venture Hutchison Baiyunshan had capital expenditures of \$21.7 million, \$13.2 million and \$7.2 million for the years ended December 31, 2015, 2016 and 2017, respectively. These capital expenditures were primarily related to the acquisition of leasehold land in Guangzhou and Bozhou as well as the construction of the new production facilities in Bozhou and an office building in Guangzhou. These capital expenditures were primarily funded through cash flows from operations of Hutchison Baiyunshan.

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

Full details of our research and development activities and expenditures are given in the "Business" and "Operating and Financial Review and Prospects" sections of this annual report above.

## D. Trend Information.

Other than as described elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our revenue, income from continuing operations, profitability, liquidity or capital resources, or that would cause our reported financial information not necessarily to be indicative of future operation results or financial condition.

# E. Off-balance Sheet Arrangements.

Other than some of the operating lease obligations set forth in the table above, we did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under the rules of the SEC.

# F. Tabular Disclosure of Contractual Obligations.

The following table sets forth our contractual obligations as of December 31, 2017. Our purchase obligations relate to property, plant and equipment that are contracted for but not yet paid. Our operating lease obligations primarily comprise future aggregate minimum lease payments in respect of various factories and offices under non-cancellable operating lease agreements.

	Payment Due by Period						
	Total	Less Than 1 Year	1-3 Years (\$'000)	3-5 Years	More Than 5 Years		
Bank borrowings	30,000	30,000	_	_	_		
Loan from a non-controlling shareholder of a							
subsidiary	1,550	1,550		_	_		
Interest on bank borrowings	480	480	_	_	_		
Interest on loan from a non-controlling							
shareholder of a subsidiary	55	55	_	_	_		
Purchase obligations	161	161	_	_	_		
Operating lease obligations	8,860	3,330	5,007	506	17		
Total	41,106	35,576	5,007	506	17		

## Shanghai Hutchison Pharmaceuticals

The following table sets forth the contractual obligations of our non-consolidated joint venture Shanghai Hutchison Pharmaceuticals as of December 31, 2017. Shanghai Hutchison Pharmaceuticals' operating lease obligations primarily comprise future aggregate minimum lease payments in respect of various factories and offices under non-cancellable operating lease agreements.

	Payment Due by Period					
	Total	Less Than 1 Year	1-3 Years (\$'000)	3-5 Years	More Than 5 Years	
Purchase obligations	574	574	_	_		
Operating lease obligations	314	283	31	_		
Total	888	857	31		_	

## Hutchison Baiyunshan

The following table sets forth the contractual obligations of our non-consolidated joint venture Hutchison Baiyunshan as of December 31, 2017. Hutchison Baiyunshan's purchase obligations comprise capital commitments for property, plant and equipment contracted for but not yet paid, which mainly relate to the construction in progress of the new production facilities at Bozhou in Anhui province. Hutchison Baiyunshan's finance and operating lease obligations primarily comprise future aggregate minimum lease payments in respect of various factories, warehouses and equipment under non-cancellable lease agreements.

	Payment Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(\$'000)		
Purchase obligations	460	460	_	_	
Finance lease obligations	543	125	250	168	
Operating lease obligations	1,707	999	520	188	
Total	2,710	1,584	770	356	_

# Quantitative and Qualitative Disclosures About Market Risk

## Foreign Exchange Risk

Substantially all of our revenue and expenses are denominated in renminbi, and our financial statements are presented in U.S. dollars. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge our exposure to such risk. 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 exchange rate between the U.S. dollar and the renminbi because the value of our business is effectively denominated in renminbi, while the ADSs will be traded in U.S. dollars.

The value of the renminbi against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in China's political and economic conditions. The conversion of renminbi into foreign currencies, including U.S. dollars, has been based on rates set by the PBOC. 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 revised policy, the renminbi is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. This change in policy resulted in a more than 20% appreciation of the renminbi against the U.S. dollar in the following three years. Between July 2008 and June 2010, this appreciation halted, and the exchange rate between the renminbi and U.S. dollar remained within a narrow band. In June 2010, the PBOC announced that the PRC government would increase the flexibility of the exchange rate, and thereafter allowed the renminbi to appreciate slowly against the U.S. dollar within the narrow band fixed by the PBOC. However, more recently, the PBOC has significantly devalued the renminbi against the U.S. dollar. 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 the renminbi would have a negative effect on the U.S. dollar amounts available to us.

# Credit Risk

Substantially all of our bank deposits are in major financial institutions, which we believe are of high credit quality. We limit the amount of credit exposure to any financial institution. We make periodic assessments of the recoverability of trade and other receivables and amounts due from related parties. Our

historical experience in collection of receivables falls within the recorded allowances, and we believe that we have made adequate provision for uncollectible receivables.

#### Interest Rate Risk

We have no significant interest-bearing assets except for bank deposits. Our exposure to changes in interest rates is mainly attributable to our bank borrowings, which bear interest at floating interest rates and expose us to cash flow interest rate risk. We have not used any interest rate swaps to hedge our exposure to interest rate risk. We have performed sensitivity analysis for the effects on our results for the year from changes in interest rates on floating rate borrowings. The sensitivity to interest rates used is based on the market forecasts available at the end of the reporting period and under the economic environments in which we operate, with other variables held constant. According to the analysis, the impact on our net loss of a 1.0% interest rate shift would be a maximum increase/decrease of \$0.4 million for the year ended December 31, 2017.

#### **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 National Bureau of Statistics of China, the Consumer Price Index in China increased by 1.4%, 2.0% and 1.8% in 2015, 2016 and 2017, respectively. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected in the future by higher rates of inflation in China.

# **Recently Issued Accounting Standards**

In May 2014, the Financial Accounting Standards Board, or FASB, issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09, to clarify the principles of recognizing revenue and create common revenue recognition guidance for U.S. GAAP and International Financial Reporting Standards. An entity has the option to apply the provisions of ASU 2014-09 either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this standard recognized at the date of initial application. ASU 2014-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2017, and early adoption is permitted but not earlier than the original effective date of December 15, 2016. The new standard supersedes U.S. GAAP guidance on revenue recognition and requires the use of more estimates, judgments and additional disclosures.

We adopted the new standard using the modified retrospective method on January 1, 2018 and have assessed the impact on revenue from customers. Our revenue from contracts with customers comprises of research and development projects in our Innovation Platform and sales of goods and services in our Commercial Platform operating segments. We expect the changes from applying the new guidance will primarily impact the Innovation Platform.

Innovation Platform—We have reviewed our research and development contracts and identified two contracts related to our license and collaboration arrangements that will be impacted by the application of ASU 2014-09. The license and collaboration arrangements contain multiple performance obligations: (1) the license to the drug compound; and (2) the research and development services for each specified treatment indication. The transaction price includes fixed and variable consideration in the form of upfront payment, research and development costs reimbursements, contingent milestone payments and sales-based royalties. The allocation of the transaction price to each performance obligation is based on the relative standalone selling price of each performance obligation. We have determined that control of the license to the drug compound was transferred as of the inception date of the collaboration agreements and consequently, amounts allocated to this performance obligation are recognized at a point in time. Conversely, control of the research and development services for each specified indication is transferred

over time and amounts allocated to these performance obligations are recognized over time using cost inputs as a measure of progress. In addition, royalty revenues will be recognized as future sales occur as they meet the requirements for the sales-usage based royalty exception. We expect US\$1.1 million deferral of revenue as a cumulative adjustment to opening accumulated loss upon adoption.

Commercial Platform—For sales of goods and services, we have applied a portfolio approach to aggregate contracts into portfolios whose performance obligations do not differ materially from each other. In our assessment of each portfolio, we have assessed the contracts under the new five-step model and do not expect a significant impact to the timing or amount of revenue recognition under the new guidance. Control of the goods passes to the customer when the goods are delivered, which matches the timing of revenue recognition under the our existing accounting policy.

We have applied updates to the new guidance in our assessment including ASU 2016-08, Principal versus Agent Considerations, ASU 2016-10, Identifying Performance Obligations and Licensing.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), or ASU 2016-02. The core principle of ASU 2016-02 is that a lessee should recognize the assets and liabilities that arise from leases. A lessee should recognize in the balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. ASU 2016-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2018. We expect to adopt the new standard using the modified retrospective method on January 1, 2019 with a retrospective adjustment to comparable periods presented starting from January 1, 2017. We are currently determining the potential impact ASU 2016-02 will have on our consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, or ASU 2017-01, which revises the definition of a business. To be considered a business, an acquisition would have to include an input and a substantive process that together significantly contribute to the ability to create outputs. To be a business without outputs, there will now need to be an organized workforce. ASU 2017-01 is effective for fiscal years and interim periods within those years beginning after December 15, 2018. We currently do not expect ASU 2017-01 to have a material impact on our consolidated financial statements, but will apply the guidance upon adoption to business acquisitions, disposals and segment changes, if any.

In May 2017, the FASB issued ASU 2017-09, Scope of Modification Accounting (Topic 718), or ASU 2017-09, which provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under share-based payment accounting. The guidance clarifies that no new measurement date will be required if there is no change to the fair value, vesting conditions, and classification, and in effect simplifies the accounting for non-substantive changes to share-based payment awards. ASU 2017-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2017. We shall apply the guidance upon adoption to share-based payment modifications, if any.

Other amendments that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

# ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

## A. Directors and Senior Management.

Below is a list of the names and ages of our directors and officers as of March 1, 2018, and a brief account of the business experience of each of them. The business address for our directors and officers is c/o Hutchison China MediTech Limited, Room 2108, 21/F, Hutchison House, 10 Harcourt Road, Hong Kong.

Name	Age	Position
Simon To	66	Executive Director and Chairman
Christian Hogg	52	Executive Director and Chief Executive Officer
Johnny Cheng	51	Executive Director and Chief Financial Officer
Weiguo Su, Ph.D.	60	Executive Director and Chief Scientific Officer
Dan Eldar, Ph.D.	64	Non-executive Director
Edith Shih	66	Non-executive Director and Company Secretary
Paul Carter	57	Senior Independent Non-executive Director
Karen Ferrante, M.D.	60	Independent Non-executive Director
Graeme Jack	67	Independent Non-executive Director
Tony Mok, M.D.	57	Independent Non-executive Director
Ye Hua, M.D.	50	Senior Vice President, Head of Clinical Development & Regulatory Affairs
May Wang, Ph.D.	54	Senior Vice President, Business Development & Strategic Alliances
Zhenping Wu, Ph.D.	58	Senior Vice President, Pharmaceutical Sciences
Mark Lee	40	Senior Vice President, Corporate Finance & Development

Simon To has been a director since 2000 and an executive director and chairman since 2006. He is also chairman of our remuneration committee and a member of our technical committee. He is managing director of Hutchison Whampoa (China) Limited and has been with Hutchison Whampoa (China) Limited for over 37 years, building its business from a small trading company to a multi-billion dollar investment group. He has negotiated major transactions with multinationals such as Procter & Gamble, or P&G, Lockheed, Pirelli, Beiersdorf, United Airlines, and British Airways. He is currently a director of Gama Aviation Plc. Mr. To's career in China spans more than 37 years. He is the original founder of Hutchison Whampoa Limited's (currently a subsidiary of CK Hutchison) China healthcare businesses and has been instrumental in its acquisitions made to date. He received a First Class Honours Bachelor's Degree in Mechanical Engineering from Imperial College, London and an MBA from Stanford University's Graduate School of Business (graduated top 5% of his class).

Christian Hogg has been an executive director and chief executive officer since 2006. He is also a member of our technical committee. He joined Hutchison Whampoa (China) Limited in 2000 and has since led all aspects of the creation, implementation and management of our strategy, business and listing. This includes the creation of our start-up businesses and the acquisition and operational integration of assets that led to the formation of our China joint ventures. Prior to joining Hutchison Whampoa (China) Limited, Mr. Hogg spent ten years with P&G, starting in the United States in Finance and then Brand Management in the Laundry and Cleaning Products Division. Mr. Hogg then moved to China to manage P&G's detergent business, followed by a move to Brussels to run P&G's global bleach business. Mr. Hogg

received a Bachelor's degree in Civil Engineering from the University of Edinburgh and an MBA from the University of Tennessee.

Johnny Cheng has been an executive director since 2011 and chief financial officer since 2008. He is also a director of Hutchison MediPharma (Hong Kong) Limited, Sen Medicine Company Limited, Hutchison MediPharma, Hutchison MediPharma (Suzhou) Limited, and Hutchison MediPharma (Yulin) Limited. He was a director of Hutchison Healthcare during 2009. Prior to joining our company, Mr. Cheng was vice president, finance of Bristol-Myers Squibb in China and was a director of Sino-American Shanghai Squibb Pharmaceuticals Ltd. and Bristol-Myers Squibb (China) Investment Co., Ltd. in Shanghai between late 2006 and 2008. Mr. Cheng started his career as an auditor with Price Waterhouse (currently PricewaterhouseCoopers) in Australia and then KPMG in Beijing before spending eight years with Nestlé in China where he was in charge of a number of finance and control functions in various operations. Mr. Cheng received a Bachelor of Economics, Accounting Major from the University of Adelaide and is a member of the Institute of Chartered Accountants in Australia.

Weiguo Su has been an executive director since 2017 and has been our chief scientific officer since 2012. He is also a member of our technical committee. Dr. Su has headed all drug discovery and research since he joined our company, including master-minding our scientific strategy, being a key leader of the Innovation Platform, and responsible for the discovery of each and every small molecule drug candidate in our pipeline. Prior to joining our company in 2005, Dr. Su spent 15 years with Pfizer's U.S. research and development organization where he became a director in their medicinal chemistry department. In March 2017, Dr. Su was granted the prestigious award by the China Pharmaceutical Innovation and Research Development Association (PhIRDA) as one of the Most Influential Drug R&D Leaders in China. Dr. Su received a Bachelor of Science degree in Chemistry from Fudan University in Shanghai and completed a Ph.D. and post-doctoral fellowship in chemistry at Harvard University under the guidance of Nobel Laureate Professor E. J. Corey.

Dan Eldar has been a non-executive director since 2016. He has more than 30 years of experience as a senior executive, leading global operations in telecommunications, water, biotech and healthcare. He is an executive director of Hutchison Water Israel Ltd which focuses on large scale projects including desalination, wastewater treatment and water reuse. He was formerly an independent non-executive director of Leumi Card, a subsidiary of Bank Leumi Le-Israel B.M., one of Israel's leading credit card companies. Dr. Eldar holds a Doctor of Philosophy degree in Government from Harvard University, Master of Arts degree in Government from Harvard University, Master of Arts degree in Political Science and Public Administration from the Hebrew University of Jerusalem and a Bachelor of Arts degree in Political Science from the Hebrew University of Jerusalem.

Edith Shih has been a non-executive director and company secretary since 2006 and company secretary of our subsidiaries since 2000. She is also an executive director and company secretary of CK Hutchison, a group she has been with since 1989, acting in the capacity of director, head group general counsel and company secretary of its subsidiaries and associated companies. Ms. Shih is a non-executive director of Hutchison Telecommunications Hong Kong Holdings Limited and Hutchison Port Holdings Management Pte. Limited, the trustee-manager of Hutchison Port Holdings Trust. She has over 35 years of experience in legal, regulatory, corporate finance, compliance and corporate governance fields. She is at present the senior vice president and an executive committee member of the Institute of Chartered Secretaries and Administrators in the United Kingdom and a past president and current council member and chairperson of various committees and panels of The Hong Kong Institute of Chartered Secretaries. Ms. Shih received a Bachelor of Science degree in Education and a Master of Arts degree from the University of the Philippines and a Master of Arts degree and a Master of Education degree from Columbia University, New York. Ms. Shih is a solicitor qualified in England and Wales, Hong Kong and Victoria, Australia and a Fellow of both the Institute of Chartered Secretaries and Administrators and The Hong Kong Institute of Chartered Secretaries.

Paul Carter has been a senior independent non-executive director since 2017. He is also a member of our audit committee, remuneration committee and technical committee. He has more than 25 years of experience in the pharmaceutical industry. From 2006 to 2016, Mr. Carter served in various senior executive roles at Gilead, a research-based biopharmaceutical company, with the last position as executive vice president, commercial operations. In this role, Mr. Carter headed the worldwide commercial organization responsible for the launch and commercialization of all of Gilead's products. Prior to joining Gilead, he spent 14 years with GlaxoSmithKline PLC and its group companies, with the last position as a regional head of the international business in Asia. He is currently a director of Alder Biopharmaceuticals, Inc. Mr. Carter holds a degree in Business Studies from the Ealing School of Business and Management (now merged into University of West London) and is a Fellow of the Chartered Institute of Management Accountants in the United Kingdom.

Karen Ferrante has been an independent non-executive director since 2017. She is also the chairman of our technical committee and a member of the audit committee. She has more than 20 years of experience in the pharmaceutical industry. She was the former chief medical officer and head of research and development of Tokai Pharmaceuticals, Inc., a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases. From September 2007 to July 2013, Dr. Ferrante held senior positions at Millennium Pharmaceuticals, Inc. and its parent company, Takeda Pharmaceutical Company Limited, including chief medical officer and most recently as oncology therapeutic area and Cambridge USA site head. From 1999 to 2007, she held positions of increasing responsibility at Pfizer Inc., with the last position as vice president, oncology development. Dr. Ferrante is currently a member of the board of directors of Progenics Pharmaceuticals, Inc., MacroGenics, Inc. and Unum Therapeutics Inc. She was previously a director of Baxalta Incorporated until it was acquired by Shire plc in 2016. Dr. Ferrante has been an author of a number of papers in the field of oncology, an active participant in academic and professional associations and symposia and holder of several patents. Dr. Ferrante holds a Bachelor of Science Degree in Chemistry and Biology from Providence College and a Doctor of Medicine from Georgetown University.

Graeme Jack has been an independent non-executive director since 2017. He is also chairman of our audit committee and member of our remuneration committee. He has more than 40 years of experience in finance and audit. He retired as partner of PricewaterhouseCoopers in 2006 after a distinguished career with the firm for over 33 years. He is currently an independent non-executive director of The Greenbrier Companies, Inc. (an international supplier of equipment and services to the freight rail transportation markets), Hutchison Port Holdings Management Pte. Limited as the trustee-manager of Hutchison Port Holdings Trust (a developer and operator of deep water container terminals) and of COSCO SHIPPING Development Co., Ltd., formerly known as "China Shipping Container Lines Company Limited" (an integrated financial services platform principally engaged in vessel and container leasing). He holds a Bachelor of Commerce degree and is a Fellow of the Hong Kong Institute of Certified Public Accountants and an Associate of Chartered Accountants Australia and New Zealand.

Tony Mok has been an independent non-executive director since 2017. He is also a member of our technical committee. Professor Mok has more than 30 years of experience in clinical oncology with his main research interest focusing on biomarker and molecular targeted therapy in lung cancer. He is currently Li Shu Fan Medical Foundation named professor and chairman of department of clinical oncology at The Chinese University of Hong Kong. Professor Mok has contributed to over 200 articles in international peer-reviewed journals, as well as multiple editorials and textbooks. He is a director of the American Society of Clinical Oncology (ASCO), a member of the ASCO Publications Committee and vice secretary of the Chinese Society of Clinical Oncology (CSCO). He also formerly chaired the ASCO International Affairs Committee. Professor Mok is closely affiliated with the oncology community in China and has been awarded an Honorary Professorship at Guangdong Province People's Hospital, Guest Professorship at Peking University School of Oncology and Visiting Professorship at Shanghai Jiao Tong University and West China School of Medicine/West China Hospital, Sichuan University. He received his

bachelor of medical science degree and a Doctor of Medicine from University of Alberta, Canada. He is also a fellow of the Royal College of Physicians and Surgeons of Canada, Hong Kong College of Physicians, Hong Kong Academy of Medicine, Royal College of Physicians of Edinburgh and ASCO.

Ye Hua has been our senior vice president and head of our clinical development & regulatory affairs group since 2014. He has 19 years' drug development and global new drug registration experience in the pharmaceutical industry, and six years' experience in cancer epidemiology. Prior to joining our company, Dr. Hua was a senior director of global clinical development at Celgene Corporation, a U.S.-based global biopharmaceutical company, from 2011 to 2014. Before joining Celgene, Dr. Hua worked as a medical director at Novartis Pharmaceuticals Corporation for eight years. Dr. Hua received his M.D. from Fudan University Shanghai medical college. He also worked as a cancer epidemiologist at the Shanghai Cancer Institute for four years before attending McGill University where he received a master's degree in cancer epidemiology.

May Wang is our senior vice president of business development & strategic alliances. Prior to joining our company in 2010, Dr. Wang spent 16 years with Eli Lilly where she was the head of Eli Lilly's Asian biology research and responsible for establishing and managing research collaborations in China and across Asia. Dr. Wang holds numerous patents, has published more than 50 peer-reviewed articles and has given dozens of seminars and plenary lectures. Dr. Wang received a Ph.D. in biochemistry from Purdue University.

Zhenping Wu joined our company in 2008 and has been our senior vice president of pharmaceutical sciences since 2012. Dr. Wu has over 25 years of experience in drug discovery and development. His past positions include senior director of pharmaceutical sciences at Phenomix Corporation, a U.S.-based biotechnology company, director of pharmaceutical development at Pfizer Global Research & Development in California (formerly Agouron Pharmaceuticals) and a group leader at Roche at its Palo Alto site. He is a past chairman and president of the board of the Sino-American Biotechnology and Pharmaceutical Association. Dr. Wu received a Ph.D. from the University of Hong Kong and a master in business administration from the University of California at Irvine.

Mark Lee is our senior vice president of corporate finance and development. Prior to joining our company in 2009, he worked in healthcare investment banking in the United States and Europe since 1998. Based in the New York and London offices of Credit Suisse, Mr. Lee was involved in the execution and origination of mergers, acquisitions, public and private financings and corporate strategy for life science companies such as AstraZeneca, Bristol-Myers Squibb and Genzyme, as well as other medical product and service companies. Mr. Lee received his bachelor's degree in biochemical engineering with first class honors from University College London, where he was awarded a Dean's Commendation. He also received a master of business administration from the Massachusetts Institute of Technology's Sloan School of Management.

# B. Compensation.

# **Executive Officer Compensation**

# Summary Compensation Table

The following table sets forth the compensation paid or accrued during the fiscal year ended December 31, 2017 to our chief executive officer, chief financial officer, chief scientific officer and other executive officers on an aggregate basis.

Name and Principal Position	Salary and fees (\$)	Bonus (\$)	Taxable benefits (\$)	Pension contributions (\$)	Total (\$)
Christian Hogg Chief Executive Officer and Executive Director	431,862 <sup>(1)(2)</sup>	769,231	15,768	26,748	1,243,609
Johnny Cheng Chief Financial Officer and Executive Director	347,758 <sup>(3)</sup>	284,872	_	24,086	656,716
Weiguo Su Chief Scientific Officer and Executive Director	310,296 <sup>(4)</sup>	1,222,071 <sup>(5)</sup>	10,000	21,132	1,563,499
Other Executive Officers in the Aggregate	980,912	1,536,307 <sup>(6)</sup>	15,291	68,450	2,600,960

- (1) Director's fees received from the subsidiaries of the Company during the period he served as director that were paid to a subsidiary or an intermediate holding company of the Company are not included in the amounts above.
- (2) Amount includes director's fees of \$75,000.
- (3) Amount includes director's fees of \$70,000.
- (4) Amount includes director's fees of \$57,534.
- (5) Amount includes a \$651,273 year-end bonus and a \$570,798 cash retention bonus (see footnote (6) below).
- (6) In December 2013 and March 2014, we awarded cash retention bonuses to certain of our executive officers in the aggregate amount of \$2,977,751. Each such executive officer receives portions of his or her retention bonus upon certain dates in the future depending on when the bonus was granted and, in each case, assuming he or she remains employed by our company on such future dates. An aggregate amount of \$848,477 of such retention bonuses was paid in 2015, an aggregate amount of \$640,399 was paid in 2016, and another aggregate amount of \$1,088,876 was paid in 2017, and such paid amount in 2017 is included in the bonus amount stated in the table above.

During the fiscal year ended December 31, 2017, we also granted share option awards representing 100,000 ordinary shares to Dr. Weiguo Su. The options have an exercise price of £31.05 (\$41.61) per share and expire on March 26, 2027. During the fiscal year ended December 31, 2017, we also granted executive officers awards under our long term incentive scheme, or LTIP, giving them a conditional right to receive ordinary shares or ADSs to be purchased by an independent third-party trustee up to a certain maximum cash amount of \$5,669,348 in the aggregate. See "Long Term Incentive Compensation" and "Outstanding Awards" for more details.

# Employment Arrangements with our Executive Officers

# Offer Letters for Executive Officers at Hutchison China MediTech Limited and Hutchison MediPharma (Hong Kong) Limited

We have entered into employment offer letters with each of our executive officers who is employed by our Hong Kong subsidiaries, Hutchison China MediTech (HK) Limited and Hutchison MediPharma (Hong Kong) Limited, namely Mr. Christian Hogg, Mr. Johnny Cheng and Mr. Mark Lee. Under these

our executives receive compensation in the form of salaries, discretionary bonuses, participation in the Hutchison Provident Fund retirement scheme, medical coverage under the Hutchison Group Medical Scheme, personal accident insurance and annual leave. None of the employment arrangements provide benefits to our executive officers upon termination. We may terminate employment by giving the executive three months' prior written notice. The executive officer may also voluntarily terminate his employment with us upon not less than three months' prior written notice to us.

Each executive officer has agreed, for the term of employment with us and thereafter, not to disclose or use for his own purposes any of our and our associated companies' confidential information that the executive officer may develop or learn in the course of employment with us. Moreover, each of our executive officers has agreed, for the term of employment with us and for a period of twelve months thereafter, (i) not to undertake or be employed or interested directly or indirectly anywhere in Hong Kong in any activity which is similar to and competitive with our company or associated companies in which the executive officer had been involved in the period of 12 months prior to such termination and (ii) not to solicit for any employees of our company or our joint ventures or orders from any person, firm or company which was at any time during the 12 months prior to termination of such employment a customer or supplier of our company or associated companies.

# Employment Agreements with Executive Officers at Hutchison MediPharma

We have also entered into employment agreements with each of our executive officers who are employed directly by Hutchison MediPharma, namely Dr. Weiguo Su, Dr. Ye Hua, Dr. May Wang and Dr. Zhenping Wu. Under these employment agreements, we engage the executive officer on either an open-ended or a fixed term. Our executive officers receive compensation in the form of salaries, discretionary bonuses, annual leave, statutory maternity leave and nursing leave.

Under the terms of these agreements, we provide labor protection and work conditions that comply with the safety and sanitation requirements stipulated by the relevant PRC laws. The employment agreements prohibit the executive officers from engaging in any conduct and business activities which may compete with the business or interests of Hutchison MediPharma during the term of the executive officer's employment. These executive officers also enjoy the Hutchison Provident Fund retirement scheme, medical coverage under the Hutchison Group Medical Scheme and personal accident insurance.

We may terminate an executive officer's employment for cause at any time without notice. Termination for cause may include a serious breach of our internal rules and policies, serious negligence in the executive officer's performance of his or her duties, an accusation or conviction of a criminal offence, acquisition of another job which materially affects the executive officer's ability to perform his or her duties for our company and other circumstances stipulated by applicable PRC laws. We may terminate an executive officer's employment with three months' prior notice if the executive officer is unable to perform his or her duties (after the expiration of the prescribed medical treatment period) because of an illness or non-work-related injury or the executive officer is incompetent and remains incompetent after training or adjustment of his or her position. The executive officer may voluntarily terminate his or her contract without cause with three months' prior notice. The executive officer may also terminate the employment agreement immediately for cause, which includes a failure by us to provide labor protection and the work conditions as specified under the employment agreement. In case of termination for any reason, we agree to make any mandatory severance payments required by the relevant PRC labor laws.

## **Share Options**

The following table sets forth information concerning the outstanding equity awards held by our chief executive officer, chief financial officer, chief scientific officer and other executive officers on an aggregate basis as of December 31, 2017.

Number of securities underlying unexercised options which are exercisable (#)	Number of securities underlying unexercised options which are unexercisable (#)	Option exercise price (£/share)	Option expiration date
_	_	_	_
_	_	_	_
300,000	100,000	19.70 31.05	Dec. 19, 2023 Mar. 26, 2027
293,686	_	19.70	Dec. 19, 2023
75,000	25,000	19.70	Jun. 27, 2024
_	50,000	31.05	Mar. 26, 2027
	securities underlying unexercised options which are exercisable (#)   300,000 293,686	securities underlying unexercised options which are exercisable (#)  — — — — — — — — — — — — — — — — — — —	securities underlying unexercised options which are exercisable (#)         securities underlying unexercised options which are unexercisable (#)         Option exercise price (£/share)           —         —         —           300,000         —         —           —         100,000         31.05           293,686         —         19.70           75,000         25,000         19.70

# Long-Term Incentive Compensation

The following table sets forth information concerning the outstanding LTIP grants held by our chief executive officer, chief financial officer, chief scientific officer and other executive officers on an aggregate basis as of December 31, 2017.

Name and Principal Position		Maximum Aggregate Value of LTIP awards <sup>(1)</sup>	
Christian Hogg	\$	1,817,884	
Chief Executive Officer and Executive Director			
Johnny Cheng	\$	690,639	
Chief Financial Officer and Executive Director			
Weiguo Su	\$	1,188,995	
Chief Scientific Officer and Executive Director			
Other Executive Officers in the Aggregate	\$	1,971,830	

(1) The amounts reflected in the table above represent the maximum aggregate value of all LTIP awards outstanding as of December 31, 2017, which include LTIP awards for the fiscal years 2015 to 2019. Certain of the LTIP awards are conditional upon the achievement of annual performance targets for the fiscal years 2017, 2018 and 2019. The amounts reflected in the table above assume the maximum amount that may be paid under these contingent LTIP awards. The LTIP awards will be settled in a variable number of shares based on a fixed monetary amount awarded upon achievement of performance targets or upon vesting, as applicable. An independent third-party trustee who administers the LTIP purchased shares of Chi-Med on either the AIM and Nasdaq market which will be used to settle the LTIP awards. See "Outstanding Awards" for more details.

# **Director Compensation**

The following table sets forth a summary of the compensation we paid to our directors other than Christian Hogg, Johnny Cheng and Weiguo Su during 2017. Other than as set forth in the table below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to such directors.

Name of Director	Fees Earned or Paid in Cash (\$)	Share option benefits (\$)	All other compensation (\$)	Total (\$)
Simon To	85,000(1)	_	_	85,000
Dan Eldar	70,000	_		70,000
Edith Shih	$70,000^{(2)}$	_	_	70,000
Paul Carter <sup>(3)</sup>	102,667		_	102,667
Karen Ferrante <sup>(3)</sup>	93,958	_	_	93,958
Graeme Jack <sup>(4)</sup>	86,667			86,667
Tony Mok <sup>(5)</sup>	18,641	_	_	18,641
Christopher Huang <sup>(6)</sup>	7,291			7,291
Christopher Nash <sup>(6)</sup>	6,875	_	_	6,875
Shigeru Endo <sup>(6)</sup>	5,833 <sup>(7)</sup>			5,833
Michael Howell <sup>(8)</sup>	15,000		_	15,000

- (1) Such director's fees were paid to Hutchison Whampoa (China) Limited, a wholly owned subsidiary of CK Hutchison. Director's fees received from our subsidiaries during the period he served as director that were paid to a subsidiary or an intermediate holding company of our company are not included in the amounts above.
- (2) Such director's fees were paid to Hutchison International Limited, a wholly owned subsidiary of CK Hutchison. Director's fees received from our subsidiaries during the period she served as director that were paid to a subsidiary or an intermediate holding company of our company are not included in the amounts above.
- (3) Appointed on February 1, 2017.
- (4) Appointed on March 1, 2017.
- (5) Appointed on October 12, 2017.
- (6) Ceased to be a director as of February 1, 2017.
- (7) Such director's fees were paid to Hutchison International Limited, a wholly owned subsidiary of CK Hutchison.
- (8) Ceased to be a director as of March 1, 2017.

# **Equity Compensation Schemes and Other Benefit Plans**

We have two share option schemes. We refer to these collectively as the Chi-Med Option Schemes. Our shareholder adopted the first Chi-Med Option Scheme, or the 2005 Chi-Med Option Scheme, in June 2005, and it was subsequently approved by the shareholders of Hutchison Whampoa Limited, our then majority shareholder, in May 2006 and later amended by our board of directors in March 2007. This share option scheme expired in 2016. In April 2015, our shareholders adopted the second Chi-Med Option Scheme, or the 2015 Chi-Med Option Scheme, which was later approved by the shareholders of CK Hutchison, the ultimate parent of our majority shareholder, in May 2016.

We also have a long-term incentive scheme which was adopted by our shareholders in April 2015. We refer to this as our LTIP.

In addition, our subsidiary Hutchison MediPharma Holdings has two share option schemes. We refer to these collectively as the Hutchison MediPharma Option Schemes. The first Hutchison MediPharma Option Scheme, or the 2008 Hutchison MediPharma Option Scheme, was adopted in August 2008 upon approval by its shareholder. The 2008 Hutchison MediPharma Option Scheme was thereafter amended by the board of directors of Hutchison MediPharma Holdings in April 2011 and expired in 2014. The second Hutchison MediPharma Option Scheme, or the 2014 Hutchison MediPharma Option Scheme, was adopted in December 2014 upon approval by its shareholders.

Our Chi-Med Option Schemes, our LTIP and the 2014 Hutchison MediPharma Option Scheme each terminate on the tenth anniversary of their adoption. Each may also be terminated by its board of directors at any time. Any termination of the scheme is without prejudice to the awards outstanding at such time. Options are no longer being granted under the 2005 Chi-Med Option Scheme or the 2008 Hutchison MediPharma Option Scheme, but outstanding awards under the 2005 Chi-Med Option Scheme continue to be governed by the terms thereof.

The following describes the material terms of our Chi-Med Option Schemes, our LTIP and the Hutchison MediPharma Option Schemes, or collectively the Schemes.

Awards and Eligible Grantees. The Schemes provide for the award of share options exercisable for ordinary shares of our company (in the case of the Chi-Med Option Schemes) or ordinary shares of Hutchison MediPharma Holdings (in the case of the Hutchison MediPharma Option Schemes) to Eligible Employees (as defined in the Chi-Med Option Schemes) or non-executive directors (excluding any independent non-executive directors under the Chi-Med Option Schemes).

Under our LTIP, awards in the form of contingent rights to receive either shares or cash payments may be granted to the directors of our company, directors of our subsidiaries and employees of our company, subsidiaries, affiliates or such other companies as determined by our board of directors in its absolute discretion.

Scheme Administration. Our board of directors has delegated its authority for administering our Chi-Med Option Schemes and our LTIP to our remuneration committee. The board of directors of Hutchison MediPharma Holdings is responsible for administering the Hutchison MediPharma Option Schemes. Each such plan administrator has the authority to, among other things, select participants and determine the amount and terms and conditions of the awards under the applicable Schemes as it deems necessary and proper, subject to the restrictions described in "—Restrictions on Grants" below.

Restrictions on Grants. Under the Chi-Med Option Schemes, grants may not be made to independent non-executive directors. Furthermore, those grants may not be made to any of our employees or directors if such person is also a director, chief executive or substantial shareholder of any of our direct or indirect parent companies which is listed on a stock exchange, including CK Hutchison, or any of its associates without approval by the independent non-executive directors of such parent company (excluding any independent non-executive director who is a proposed grantee). In addition, approval by our shareholders and the shareholders of such listed parent company is required if an option grant under the Chi-Med Option Schemes is to be made to a substantial shareholder or independent non-executive director of a listed parent company or any of its associates and, upon exercise of such grant and any other grants made during the prior 12-month period to that shareholder, that individual would receive an amount of our ordinary shares equal or greater than 0.1% of our total outstanding shares or with an aggregate value in excess of HK\$5 million (equivalent to \$0.6 million as of December 31, 2017). The Hutchison MediPharma Option Schemes do not contain these restrictions.

In addition, options under our Chi-Med Option Schemes and the Hutchison MediPharma Option Schemes may not be granted to any individual if, upon the exercise of such options, the individual would receive an amount of shares when aggregated with all other options granted to such individual under the applicable Scheme in the 12-month period up to and including the grant date, that exceeds 1% of the total

shares outstanding of the company granting the award on such date. In the event a grant of share options would exceed 1% of the total number of issued shares of Hutchison MediPharma Holdings, our company must also approve the grant. There are no individual limits under the LTIP.

Under our LTIP, no grant to any director, chief executive or substantial shareholder of our company may be made without the prior approval of our independent non-executive directors (excluding an independent non-executive director who is a proposed grantee).

Vesting. Vesting conditions of options granted under the Schemes are determined by the respective board of directors at the time of grant. Any options granted are normally exercisable to the extent vested within the period specified by the applicable Scheme, which ranges from six to ten years after the date of grant.

Under the Chi-Med Share Option Schemes and the Hutchison MediPharma Option Schemes, if a participant has committed any misconduct or any conduct making such participant's service terminable for cause, all options (whether vested or unvested) lapse unless the respective board of directors otherwise determines in its absolute discretion. Options may be exercised to the extent vested where a participant's service ceases due to the participant's death, serious illness, injury, disability, retirement at the applicable retirement age, or earlier if determined by the participant's employer, or if a participant's service ceases for any other reason other than for cause.

Under the LTIP, if a participant's employment or service with our company or its subsidiaries is terminated for cause or if the participant breaches certain provisions in the LTIP restricting the transfer of awards by grantees and imposing non-competition obligations on grantees, all unvested awards are automatically cancelled. Where a participant's employment or service ceases for any reason other the reasons listed above (including due to the participant's resignation, retirement, death or disability or upon the non-renewal of such participant's employment or service agreement other than for cause), our board of directors may determine at its discretion whether unvested awards shall be deemed vested.

Exercise Price. The exercise price for each share pursuant to the initial options granted under the 2005 Chi-Med Option Scheme was a price determined by our board of directors at the date of grant, and for grants made thereafter, the exercise price was the Market Value of a share at the date of grant (as defined in the Chi-Med Option Schemes). The exercise price for each share pursuant to options granted under our 2008 Hutchison MediPharma Option Scheme was a price determined by the board of directors of Hutchison MediPharma Holdings.

The exercise price for each share pursuant to the options granted under the 2015 Chi-Med Option Scheme must be the Market Value of a share at the date of grant (as defined in the Chi-Med Option Schemes). The exercise price for each share pursuant to options granted under the 2014 Hutchison MediPharma Option Scheme will be determined by the boards of directors of Hutchison MediPharma Holdings at the date of grant.

Non-transferability of Awards. Awards may not be transferred except in the case of a participant's death by the terms of each Scheme.

Takeover or Scheme of Arrangement. In the event of a general or partial offer for the shares of our company (under the Chi-Med Option Schemes) or Hutchison MediPharma Holdings (under the Hutchison MediPharma Option Schemes), whether by way of takeover, offer, share repurchase offer, or scheme of arrangement, the affected company is required to use all reasonable endeavors to procure that such offer is extended to all holders of options granted by such company on the same terms as those applying to shareholders. Both vested and unvested options may be exercised up until (i) the closing date of any such offer, (ii) the record date for entitlements under a scheme of arrangement, or (iii) two business days prior to any general meeting of members convened to consider such offer (under the 2014 Hutchison

MediPharma Option Scheme), and will lapse thereafter. Certain options may also be exercised on a voluntary winding up of our company or Hutchison MediPharma Holdings, as the case may be.

Under our LTIP, in the event of a general offer for all the shares of our company, whether by way of takeover or scheme of arrangement, or if our company is to be voluntarily wound up, our board of directors shall determine in its discretion whether outstanding unvested awards will vest and the period within which such awards will vest.

Amendment. The Chi-Med Option Schemes require that amendments of a material nature only be made with the approval of our shareholders and approval of any of our direct or indirect parent companies which is listed on a stock exchange, including CK Hutchison. The Hutchison MediPharma Option Schemes may be altered by the board of directors of our company or Hutchison MediPharma Holdings, as the case may be, but any amendments which provide a material advantage to grantees cannot take effect without shareholders' approval.

Our board of directors may alter the LTIP, but amendments which are of a material nature cannot take effect without shareholders' approval, unless the changes take effect automatically under the terms of the LTIP.

Authorized Shares. Subject to certain adjustments for share splits, share consolidations and other changes in capitalization, the maximum number of shares that may be issued upon exercise of all options granted may not in the aggregate exceed: (i) 4% of our shares outstanding on the date of adoption of the 2015 Chi-Med Option Scheme or (ii) 5% of the shares of Hutchison MediPharma Holdings outstanding on the date of adoption under the 2014 Hutchison MediPharma Option Scheme. In addition, under our 2015 Chi-Med Option Scheme, our board of directors may, with the approval of the shareholders of any of our direct or indirect parent companies which is listed on a stock exchange, including CK Hutchison, "refresh" the 4% scheme limit provided that the total number of shares which may be issued upon exercise of all options to be granted under the Chi-Med Option Schemes shall not exceed 10% of our total shares outstanding on such date. Further, the maximum number of shares that may be issued upon exercise of all options granted and not yet exercised under the 2015 Chi-Med Option Scheme, when combined with options granted and not yet exercised under any other schemes of our company or our subsidiaries must not exceed 10% of our shares outstanding on such date.

Share awards under our LTIP may not exceed 5% of our shares outstanding on the adoption date of the LTIP.

# **Outstanding Awards**

As of December 31, 2017, the following options were outstanding:

- options to purchase an aggregate of 282,726 ordinary shares, representing approximately 0.4% of our outstanding share capital, at a weighted average exercise price of £5.65 per share under the 2005 Chi-Med Option Scheme, and
- options to purchase an aggregate of 843,686 ordinary shares, representing approximately 1.3% of the outstanding share capital, at a weighted average exercise price of £21.72 per share under the 2015 Chi-Med Option Scheme.

In March 2017, we granted awards under our LTIP to 89 senior managers, executives and directors, giving each a conditional right to receive ordinary shares to be purchased by an independent third-party trustee up to a certain maximum cash amount of \$5,919,545 per annum depending upon the achievement of annual performance targets from 2017 to 2019. Any ordinary shares purchased on behalf of an LTIP grantee are to be held by the trustee until they are vested. Vesting will occur two business days after the date of announcement of the annual results for the financial year falling two years after the financial year

to which the LTIP award relates. Vesting will also depend upon the continued employment of the award holder and will otherwise be at the discretion of our board of directors.

In March 2017, we also granted additional LTIP awards to 31 senior managers, executives and directors, giving them a conditional right to receive ordinary shares to be purchased by the third-party trustee up to an aggregate maximum cash amount of \$353,243. These awards are not related to the achievement of performance targets. These LTIP awards vest after one year, subject to the continued employment of the LTIP holder.

In August 2017, we granted awards under our LTIP to two senior executives, giving each a conditional right to a cash amount which is used to purchase shares by an independent third-party trustee up to a certain maximum cash amount of \$64,827 per annum depending upon the achievement of annual performance targets from 2017 to 2019. Vesting will occur two business days after the date of announcement of the annual results for the financial year falling two years after the financial year to which the LTIP award relates.

In December 2017, we granted awards under our LTIP to ten senior executives, giving each a conditional right to a cash amount which is used to purchase ordinary shares by an independent third-party trustee up to a certain maximum cash amount of \$529,477 per annum depending upon the achievement of annual performance targets from 2018 to 2019. Vesting will occur two business days after the date of announcement of the annual results for the financial year falling two years after the financial year to which the LTIP award relates.

## C. Board Practices.

Our board of directors consists of ten directors including four executive directors, two non-executive directors and four independent non-executive directors. Pursuant to a relationship agreement dated April 21, 2006 by and between our company and Hutchison Whampoa (China) Limited, a parent company of Hutchison Healthcare Holdings Limited, or the Relationship Agreement, our board of directors must consist of at least one director who is independent of the Hutchison Whampoa Limited group so long as Hutchison Whampoa (China) Limited is entitled to cast at least 50% votes eligible to be cast on a poll vote at a general meeting of our company. The Relationship Agreement will continue in effect until our ordinary shares cease to be traded on the AIM market or the CK Hutchison group individually or collectively ceases to hold at least 30% of our shares.

Our directors are subject to a three-year term of office and hold office until such time as they wish to retire and not offer themselves up for re-election, are not re-elected by the shareholders, or are removed from office by special resolution at an annual general meeting of the shareholders. Under our articles of association, 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) is found to be or becomes of unsound mind. For information regarding the period during which our officers and directors have served in their respective positions, please see Item 6.A. "Directors and Senior Management."

# **Board Committees**

Our board of directors has established an audit committee, a remuneration committee and a technical committee.

## **Audit Committee**

Our audit committee consists of Graeme Jack, Paul Carter and Karen Ferrante, with Graeme Jack serving as chairman of the committee. Michael Howell, Christopher Huang and Christopher Nash previously served on our audit committee until they resigned from our board of directors on March 1, 2017, February 1, 2017 and February 1, 2017, respectively. Graeme Jack, Paul Carter and Karen Ferrante

each meet the independence requirements under the rules of the Nasdaq Stock Market and under Rule 10A-3 under the Exchange Act. We have determined that Graeme Jack is an "audit committee financial expert" within the meaning of Item 407 of Regulation S-K. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Stock Market.

Although we are a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Rule 10A-3 provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditor, as well as control over the performance of their duties, management of complaints made, and selection of consultants. Under Rule 10A-3, if the governing law or documents, of a listed issuer require that any such matter be approved by the board of directors or the shareholders of the company, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Our articles of association provide that the audit committee may only have an advisory role and appointment of our auditor must be decided by our shareholders at our annual general meeting or at a subsequent extraordinary general meeting in each year.

The audit committee formally meets at least twice a year and otherwise as required. The audit committee's purpose is to oversee our accounting and financial reporting process and the audit of our financial statements. Our audit committee's primary duties and responsibilities are to:

- monitor the integrity of our financial statements, our annual and half-year reports and accounts and our announcements of interim or final results;
- review significant financial reporting issues and the judgments which they contain;
- review, whenever practicable without being inconsistent with any requirement for prompt reporting under applicable listing rules, other statements containing financial information such as significant financial returns to regulators and release of price sensitive information first where board of director approval is required; and
- review and challenge where necessary:
  - the consistency of, and any changes to, accounting policies both on a year-on-year basis and across our company;
  - the methods used to account for significant or unusual transactions where different approaches are possible;
  - whether our company has followed appropriate accounting standards and made appropriate estimates and judgments, taking into account the views of the external auditor;
  - the clarity of the disclosure in our financial reports and the context in which statements are made; and
  - all material information presented with the financial statements, such as any operating and financial review and any corporate governance statements (insofar as it relates to the audit and risk management).

In relation to our internal controls and risk management systems, our audit committee, among other things:

- reviews the effectiveness of our internal control and risk management systems;
- reviews the policies and procedures for the identification, assessment and reporting of financial and non-financial risks and our management of those risks in accordance with the requirements of the Sarbanes-Oxley Act and other applicable laws, rules and regulations and the applicable requirements of any stock exchange;

- approves the appointment and removal of the head of the internal audit function;
- ensures our internal audit function has adequate standing and resources and is free from management or other restrictions;
- reviews and monitors our executive management's responsiveness to the findings and recommendations of the internal audit function; and
- reviews with management and our independent auditors the adequacy and effectiveness of our internal control over financial reporting and disclosure controls and procedures.

In relation to our external auditor, our audit committee, among other things:

- recommends the appointment, reappointment or removal of the external auditor and considers any
  issues relating to their resignation, dismissal, remuneration or terms of engagement, subject to
  approval by the shareholders;
- considers and monitors the external auditor's independence, objectivity and effectiveness;
- reviews and monitors the effectiveness of the audit process, considering relevant ethical or professional requirements;
- develops and implements policy on the engagement of the external auditor to provide non-audit services, taking into any relevant ethical guidance; and
- pre-approves the external auditors' annual audit fees and the nature and scope of proposed audit coverage, subject to approval by our shareholders.

The audit committee is authorized to obtain, at our company's expense, reasonable outside legal or other professional advice on any matters within the scope of its responsibilities.

## **Remuneration Committee**

Our remuneration committee consists of Simon To, Graeme Jack and Paul Carter, with Simon To serving as chairman of the committee. Michael Howell and Christopher Nash previously served on our remuneration committee until they resigned from our board of directors on March 1, 2017 and February 1, 2017, respectively. The remuneration committee is responsible for considering all material elements of remuneration policy and remuneration and incentives of our executive directors and key employees with reference to independent remuneration research and professional advice. The remuneration committee meets formally at least once each year and otherwise as required and make recommendations to our board of directors on the framework for executive remuneration and on proposals for the granting of share options and other equity incentives. Our board of directors is responsible for implementing these recommendations and agreeing the remuneration packages of individual directors. No director is permitted to participate in discussions or decisions concerning his or her own remuneration.

# **Technical Committee**

Our technical committee consists of Karen Ferrante, Paul Carter, Tony Mok, Simon To, Christian Hogg and Weiguo Su, with Karen Ferrante serving as chairman of the committee. Christopher Huang previously served as chairman and member of our technical committee until he resigned from our board of directors on February 1, 2017. The technical committee's responsibility is to consider, from time to time, matters relating to the technical aspects of the research and development activities of our Innovation Platform. It invites such executives as it deems appropriate to participate in meetings from time to time.

## **U.K.** Corporate Governance Code

We have voluntarily applied, and plan to continue to apply for the foreseeable future, the principles of the U.K. Corporate Governance Code published by the U.K. Financial Reporting Council. The U.K. Corporate Governance Code is the primary source of corporate governance standards for companies in the United Kingdom, and it is recognized as a best practice for companies whose shares are admitted to trading on the AIM market of the London Stock Exchange.

The U.K. Corporate Governance Code is comprised of main and supporting principles of good governance addressing the following areas: director practices, directors' remuneration, accountability and audit and relations with shareholders and institutional investors. It also includes detailed recommendations derived from these principles, such as: the roles of board chairman and chief executive officer should not be exercised by the same individual and the chairman of the board should ensure that new directors receive a full, formal and tailored induction on joining the board.

Except for general fiduciary duties and duties of care, Cayman Islands law has no specific corporate governance regime which prescribes specific corporate governance standards on our directors. See Item 16G. "Corporate Governance" for a discussion of such Cayman Islands law requirements applicable to our company.

## **Code of Ethics**

Our board of directors has adopted a code of ethics to set standards for our directors, officers and employees as are reasonably necessary to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely and understandable disclosure in the reports and documents that we file or submit to the applicable stock exchanges, and in any other public communications; (iii) compliance with applicable governmental and regulatory laws, rules, codes and regulations; (iv) prompt internal reporting of any violations of the code of ethics; and (v) accountability for adherence to the code of ethics.

## **Code of Ethics for Business Partners**

Our board of directors has adopted a code of ethics for our business partners, including our suppliers, vendors, customers, agents, contractors, joint venture partners and representatives. This code of ethics contains general guidelines to promote the standards outlined in our internal code of ethics as described above.

## **Complaints Procedures**

Our board of directors has adopted procedures for the confidential receipt, retention, and treatment of complaints from, or concerns raised by, employees regarding accounting, internal accounting controls and auditing matters as well as illegal or unethical matters. The complaint procedures are reviewed by the audit committee from time to time as warranted to ensure their continuing compliance with applicable laws and listing standards as well as their effectiveness.

## **Information Security Policy**

Our board of directors has adopted an information security policy to define and help communicate the common policies for information confidentiality, integrity and availability to be applied to us and our joint ventures. The purpose of the information security policy is to ensure business continuity by preventing and minimizing the impact of security risks within our company and our joint ventures. Our information security policy applies to all of our and our joint ventures' business entities across all countries. It applies to the creation, communication, storage, transmission and destruction of all different types of information. It applies to all forms of information, including but not limited to electronic copies, hardcopy, and verbal disclosures whether in person, over the telephone, or by other means.

## Code on Dealings in Shares

Our board of directors has adopted a policy on the handling of material inside information, consisting of information which is either "inside information" under the EU Market Abuse Regulation (Regulation (EU) 596/2014), or MAR, or "material non-public information" under U.S. law. This policy, among other things, prohibits any employees, directors, other persons discharging managerial responsibilities or their connected persons dealing in our securities or their derivatives, or those of our collaborators, business partners, suppliers and customers, while in possession of material inside information. Certain members of our senior management or staff, including persons discharging managerial responsibilities, and their connected persons are subject to additional compliance requirements which are outlined in the code (including but not limited to obtaining written pre-clearance from designated members of management prior to any dealing in any such securities is allowed).

# **Board Diversity Policy**

Our board of directors has established a board diversity policy as our board of directors recognizes the benefits of a board of directors that possesses a balance of skills, experience, expertise, independence and knowledge and diversity of perspectives appropriate to the requirements of our businesses.

We maintain that appointment to our board of directors should be based on merit that complements and expands the skills, experience, expertise, independence and knowledge of the board of directors as a whole, taking into account gender, age, professional experience and qualifications, cultural and educational background, and any other factors that our board of directors might consider relevant and applicable from time to time towards achieving a diverse board of directors.

# D. Employees.

As of December 31, 2015, 2016 and 2017, we had 451, 563 and 590 full-time employees, respectively. None of our employees are represented by labor unions or covered by collective bargaining agreements. The number of employees by function as of the end of the period for our fiscal years ended December 31, 2015, 2016 and 2017 was as follows:

	2017	2016	2015
By Function:			
Innovation Platform	358	329	281
Commercial Platform	205	209	149
Corporate Head Office	27	25	21
Total	590	563	451

As of December 31, 2017, a total of 75 employees on our Innovation Platform's research and development team have M.D. or Ph.D. degrees. Additionally, our Commercial Platform joint venture Shanghai Hutchison Pharmaceuticals employed a total of 2,911 full-time employees, and Hutchison Baiyunshan employed a total of 1,711 full-time employees and 1,688 outsourced contract staff, who are mostly sales representatives and manufacturing employees as of December 31, 2017. Their employees are represented by labor unions and covered by collective bargaining agreements. To date, neither Shanghai Hutchison Pharmaceuticals nor Hutchison Baiyunshan has experienced any strikes, labor disputes or industrial actions which had a material effect on their business, and consider their relations with the union and our employees to be good.

# E. Share Ownership.

See Item 6 B. "Compensation" and Item 7 "Major Shareholders and Related Party Transactions."

#### ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

#### A. Major Shareholders.

We had 66,447,037 ordinary shares outstanding as of December 31, 2017. The following table and accompanying footnotes set forth information relating to the beneficial ownership of our ordinary shares as of December 31, 2017 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding ordinary shares;
- each of our directors; and
- each of our named executive officers.

Our major shareholders do not have voting rights that are different from our shareholders in general. Beneficial ownership is determined in accordance with the rules and regulations of the SEC.

	Number of Ordinary	Number of American Depositary	Approximate Percent of Issued Share
Name of beneficial owner	Shares Held	Shares Held	Capital <sup>†</sup>
Executive Officers and Directors:**			
Christian Hogg	1,093,802	40,356	1.7%
Johnny Cheng	256,146	4,626	*
Simon To	180,000	133,237	*
Edith Shih	70,000	100,000	*
Weiguo Su	$300,000^{(1)}$	56,546	*
Dan Eldar	1,900	6,225	*
Tony Mok	_	10,002	*
Paul Carter	3,524	_	*
Karen Ferrante	_	5,785	*
Graeme Jack	_	_	_
Ye Hua	*	*	*
May Wang	*	*	*
Zhenping Wu	*	*	*
Mark Lee	*	*	*
All Executive Officers and Directors as a Group	$2,280,665^{(2)}$	364,665	3.7%
Principal Shareholder:			
Hutchison Healthcare Holdings Limited <sup>(3)</sup>	36,666,667	6,862,420	60.4%

<sup>\*</sup> Less than 1% of our total outstanding ordinary shares.

- † Percentage of beneficial ownership of each listed person or group is based on 66,447,037 ordinary shares outstanding as of December 31, 2017.
- (1) Amount includes ordinary shares issuable upon vesting of options within 60 days of December 31, 2017.
- (2) Amount includes ordinary shares and ordinary shares issuable upon vesting of options within 60 days of December 31, 2017 held by our executive officers and directors as group.
- (3) Hutchison Healthcare Holdings Limited, a British Virgin Islands company, is an indirect wholly owned subsidiary of CK Hutchison, a company incorporated in the Cayman Islands and listed on the Hong Kong Stock Exchange. The registered address of Hutchison Healthcare Holdings Limited is

<sup>\*\*</sup> The business address of all the directors and officers is Room 2108, 21/F, Hutchison House, 10 Harcourt Road, Hong Kong.

Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola VG1110, British Virgin Islands.

As of December 31, 2017, based on public filings with the SEC and on AIM, there are no major shareholders holding 5% or more of our ordinary shares or ADSs representing ordinary shares, except as described above. As of December 31, 2017, there was one ordinary shareholder of record with an address in the United States. Deutsche Bank Trust Company America, the depositary of our ADS program, held 11,708,338 ordinary shares as of that date in the name of DB London (Investors Services) Nominees Limited and Deutsche Bank AG.

To our knowledge, except as disclosed above, we are not owned or controlled, directly or indirectly, by another corporation, by any foreign government or by any other natural or legal person or persons, severally or jointly. To our knowledge, there are no arrangements the operation of which may at a subsequent date result in us undergoing a change in control. Our major shareholders do not have different voting rights than any of our other shareholders.

## B. Related Party Transactions.

## Relationship with CK Hutchison

## Letters of awareness with respect to loans

CK Hutchison has issued letters of awareness to our lenders Scotiabank (Hong Kong) Limited, Bank of America N.A. and Deutsche Bank AG, Hong Kong Branch, and committed not to reduce its shareholding to less than 40% of our issued share capital while such loans are outstanding. Hutchison Whampoa Limited, a wholly owned subsidiary of CK Hutchison, guaranteed our previous term loan with Scotiabank until such loan was fully repaid in November 2017. For the year ended December 31, 2017, we paid a guarantee fee of \$0.3 million to Hutchison Whampoa Limited.

See Item 3.D. "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—If the CK Hutchison group ceases to own a majority stake in our company, we may incur significantly higher borrowing costs."

### Relationship Agreement with the CK Hutchison group

We entered into a relationship agreement dated April 21, 2006 with Hutchison Whampoa (China) Limited, which is an indirect wholly owned subsidiary of CK Hutchison, with a view to ensuring that our company is capable of carrying on its business independently of the CK Hutchison group. We refer to this agreement as the Relationship Agreement. The Relationship Agreement provides, among other things, that all transactions between any of us or our joint ventures, on the one hand, and the CK Hutchison group, on the other hand, will be on an arm's length basis, on normal commercial terms and in a manner consistent with the AIM Rules. Hutchison Whampoa (China) Limited has agreed that, so long as it holds shares (either directly or indirectly) which in aggregate entitle Hutchison Whampoa (China) Limited to cast at least 50% of the votes eligible to be cast on a poll vote at a general meeting of our company, it shall procure (so far as it is able to use its power as a shareholder) that at least one member of our board of directors is independent of the CK Hutchison group. The Relationship Agreement further provides that the approval of our board of directors shall be required for any transaction between any of us or our joint ventures, on one hand, and the CK Hutchison group, on the other hand, and that in approving any such transaction, our board of directors must consist of at least one director who is independent of CK Hutchison. Hutchison Whampoa (China) Limited has also agreed to procure that each member of the Hutchison Whampoa (China) Limited group will not exercise its voting rights and powers so as to amend our memorandum or articles of association in a manner which is inconsistent with the Relationship Agreement. The Relationship Agreement will continue until the first to occur of: (i) our shares ceasing to

be traded on the AIM market or (ii) the CK Hutchison group individually or collectively cease to hold or control the exercise of at least 30% or more of the rights to vote at our general meetings.

## Products sold to group companies of CK Hutchison

We have entered into agreements with members of the CK Hutchison group, including the retail grocery and pharmacy chains PARKnSHOP and Watsons which are owned and operated by the A.S. Watson Group, an indirect subsidiary of CK Hutchison, in respect of the distribution of certain of our Commercial Platform products. For the year ended December 31, 2017, sales of our products to members of the CK Hutchison group amounted to \$8.5 million. In addition, for the year ended December 31, 2017, we paid approximately \$0.4 million to members of the CK Hutchison group for the provision of marketing services associated with these products. Our sales to CK Hutchison group companies are made pursuant to purchase orders issued by each purchaser periodically, the terms of which are on an arm's length basis on normal commercial terms.

See Item 3.D. "Risk Factors—Risks Related to our Dependence on Third Parties—There is no assurance that the benefits currently enjoyed by virtue of our association with CK Hutchison will continue to be available" for more information on the risks associated with our relationship with CK Hutchison's group companies.

## Intellectual property licensed by the CK Hutchison group

We conduct our business using trademarks with various forms of the "Hutchison," "Chi-Med" and "China-MediTech" brands, as well as domain names incorporating some or all of these trademarks. We have entered into a brand license agreement dated April 21, 2006 with Hutchison Whampoa Enterprises Limited, which is an indirect wholly owned subsidiary of CK Hutchison, pursuant to which we have been granted a non-exclusive, non-transferrable, royalty-free right to use such trademarks, domain names and other intellectual property rights owned by the CK Hutchison group in connection with the operation of our business worldwide. We refer to this agreement as the Brand License Agreement. We are also permitted to sub-license such intellectual property rights to our affiliates.

The Brand License Agreement contains provisions on quality control pursuant to which we are obliged to use the brands and related materials in compliance with the brand guidelines, industry best practice and other quality directives issued by Hutchison Whampoa Enterprises Limited from time to time. Under this agreement, we assign all intellectual property rights, including future copyrights in any works incorporating brand-related material or translations thereof, to Hutchison Whampoa Enterprises Limited (subject to any third-party rights).

Hutchison Whampoa Enterprises Limited may terminate the Brand License Agreement (or any sub-license) if, among other things, we commit a material breach of the agreement, or within any twelvemonth period aggregate direct or indirect shareholding in our company held by Hutchison Whampoa Limited, our indirect shareholder, is reduced to less than 50%, 40%, 30% or 20%. On termination of the Brand License Agreement, we (and any sub-licensees) must immediately cease using the brands and are obliged to withdraw from sale any products bearing the brands; provided that if the agreement is terminated following a change in Hutchison Whampoa Limited's aggregate direct or indirect shareholding in our company, we will have a six-month transitional period during which we can continue to use the licensed rights. Hutchison Whampoa Limited's interest in our company is less than 20%, but we do not anticipate that Hutchison Whampoa Enterprises Limited will terminate such license in the foreseeable future.

Hutchison Whampoa Enterprises Limited has also granted a royalty-free license to use the Hutchison name and associated trademarks to Hutchison Baiyunshan. The license has a term equal to the operational period of the joint venture but may be terminated by the licensor if, among other things, Hutchison Baiyunshan is in breach of the terms of the license and fails to remedy that breach after an arbitration

award is issued against Hutchison Baiyunshan, the joint venture agreement terminates, or our company's interest in Hutchison Baiyunshan falls below 50%.

# Sharing of services with the CK Hutchison group

Pursuant to an amended and restated services agreement dated January 1, 2016 between us and Hutchison Whampoa (China) Limited, an indirect wholly owned subsidiary of CK Hutchison, we share certain services with and receive operational support from the CK Hutchison group including, among others, legal and regulatory services, company secretarial support services, tax and internal audit services, shared use of accounting software system and related services, participation in the CK Hutchison group's pension, medical and insurance plans, participation in the CK Hutchison group's procurement projects with third-party vendors/suppliers, other staff benefits and staff training services, company functions and activities and operation advisory and support services. This amended and restated services agreement replaces our prior services agreement with Hutchison Whampoa (China) Limited, dated April 21, 2006, which had substantially similar terms. We refer to this amended and restated agreement as the Services Agreement. We pay a management fee to Hutchison Whampoa (China) Limited for the provision of such services. In addition, we make payments under the Services Agreement to Hutchison Whampoa (China) Limited for our executive offices in Hong Kong. Furthermore, pursuant to the terms of the Services Agreement, Hutchison Whampoa (China) Limited charges us management fees and other costs through Hutchison Healthcare Holdings Limited, its wholly owned subsidiary.

The Services Agreement may be terminated by either party by giving three months' written notice. Hutchison Whampoa (China) Limited may also immediately terminate if its shareholding in our company falls below 30%. The services provided under the Services Agreement are provided on an arm's length basis, on normal commercial terms.

Any amount unpaid after 30 days accrues interest at the rate of 1.5% per annum. In the year ended December 31, 2017, we paid a management fee of approximately \$0.9 million under the Services Agreement. As of December 31, 2017, we had \$0.5 million in unpaid fees outstanding to Hutchison Whampoa (China) Limited. In the year ended December 31, 2017, we paid interest in respect of unpaid fees amounting to \$0.1 million.

#### Subscription for ADSs by Hutchison Healthcare

In connection with our underwritten public offering in 2017, Hutchison Healthcare Holdings Limited subscribed for 6,862,420 ADSs for gross consideration of approximately \$181.9 million.

#### Relationships with our Joint Ventures

#### **Nutrition Science Partners**

Research and development services provided to Nutrition Science Partners. On March 25, 2013, we entered into a research and development collaboration agreement with Nestlé Health Science under which we provide certain research and development services to Nutrition Science Partners. On the same date, in connection with that agreement, we entered into a services agreement with our non-consolidated joint venture Nutrition Science Partners to provide it with the research and development services in relation to the HMPL-004 project, including: (i) collection, monitoring, processing and distribution of adverse event reports and safety and medical information including side-effects; (ii) development of manufacturing and analytical technologies for raw materials for the drug candidate being developed by such joint venture, HMPL-004; (iii) quality control and assurance of product manufacturing management; and (iv) ongoing discovery research and non-clinical support for the development of HMPL-004 and its reformulations such as HM004-6599. We provide these services on a fee-for-service basis. See Item 4.B. "Business Overview—Overview of Our Collaborations" for more information. For the year ended December 31, 2017, we

received approximately \$8.9 million for the provision of these research and development services to Nutrition Science Partners.

Intellectual property rights provided to Nutrition Science Partners. Under the terms of an assignment agreement dated November 26, 2013, we have assigned full title to intellectual property rights in connection with the HMPL-004/HM004-6599 compound on a worldwide basis to Nutrition Science Partners in exchange for \$30 million paid by Nutrition Science Partners to us.

Loans provided to Nutrition Science Partners. We and Nestlé Health Science, our joint venture partner in Nutrition Science Partners, had each provided a loan in the principal amount of \$5.0 million to Nutrition Science Partners under loan agreements each dated June 10, 2014, which were amended on August 24, 2015. After such amendments, each of the loans has a two-year renewable term with a maturity date of June 9, 2016. In addition, we and Nestlé Health Science have each provided a loan in the principal amount of \$2.0 million to Nutrition Science Partners under loan agreements each dated August 24, 2015. During 2016, we and Nestlé Health Science agreed to waive the \$7.0 million in loans to Nutrition Science Partners, and each party capitalized the outstanding amount as share capital. Additionally, in 2016 we provided \$5.0 million in share capital to Nutrition Science Partners, with Nestlé Health Science providing the same amount. In February 2017, we and Nestlé Health Science each contributed an additional \$7.0 million share capital funding to Nutrition Science Partners.

### **Hutchison Sinopharm**

Shanghai Hutchison Pharmaceuticals' provision of promotion and marketing services to Hutchison Sinopharm. On September 29, 2014 and January 29, 2015, our consolidated joint venture Hutchison Sinopharm entered into agreements with multinational pharmaceutical manufacturers Merck Serono and AstraZeneca, respectively, to market and distribute in China certain of their drugs, primarily Concor and Seroquel. In connection with Hutchison Sinopharm's agreements with Merck Serono and AstraZeneca, Hutchison Sinopharm entered into agreements with our non-consolidated joint venture Shanghai Hutchison Pharmaceuticals to provide certain promotion and marketing services within China for these drugs. Under these agreements, Shanghai Hutchison Pharmaceuticals manages marketing and is paid a service fee for medical sales services, and Hutchison Sinopharm manages distribution and logistics for these products. In the year ended December 31, 2017, Hutchison Sinopharm paid Shanghai Hutchison Pharmaceuticals \$10.2 million in connection with the provision of such services.

Hutchison Sinopharm's purchase of products from Hutchison Baiyunshan. On April 22, 2014, Hutchison Sinopharm entered into distribution agreements to purchase certain products manufactured by our non-consolidated joint venture Hutchison Baiyunshan. Under the terms of these agreements, Hutchison Sinopharm manages the distribution and delivery logistics of such products.

Hutchison Sinopharm's distribution agreement with Hutchison Baiyunshan has a one-year term. Hutchison Baiyunshan may terminate the agreement prior to that if Hutchison Sinopharm fails to purchase products from Hutchison Baiyunshan for three consecutive months, fails to achieve sales target, engages in sales outside of Shanghai, engages in unfair competition practices or distributes the products through channels other than hospitals without Hutchison Baiyunshan's consent. Hutchison Sinopharm and Hutchison Baiyunshan are in the process of renewing their agreement for the distribution of products.

In the year ended December 31, 2017, Hutchison Sinopharm purchased products from Hutchison Baiyunshan for an amount totaling \$0.9 million in the aggregate.

Hutchison Healthcare's grant of license to distribute Zhi Ling Tong products to Hutchison Sinopharm. In January 2016, Hutchison Healthcare granted a license to Hutchison Sinopharm to distribute Chi-Med-owned Zhi Ling Tong infant nutrition products, which had previously been distributed by a third-party distributor. Under such license, Hutchison Sinopharm obtains exclusive distribution rights for Zhi

Ling Tong infant nutrition products from Hutchison Healthcare within China which are subject to annual renewal reviews. The distribution rights were renewed for 2017.

#### Hutchison Hain Organic

Loans to Hutchison Hain Organic (Hong Kong) Limited. We and Hain Celestial have each provided a loan in the principal amount of \$2.55 million to Hutchison Hain Organic (Hong Kong) Limited, a wholly owned subsidiary of our joint venture Hutchison Hain Organic, under loan agreements dated December 24, 2014. On July 15, 2016, Hutchison Hain Organic (Hong Kong) Limited repaid \$1.0 million to each of us and Hain Celestial, after which \$1.55 million remain outstanding under each loan agreement. Each of the loans has a four-year renewable term with a maturity date of October 8, 2018. Each loan bears an interest rate equal to the 3-month LIBOR plus 3% per annum, payable at maturity. As of December 31, 2017, all such principal amounts remained outstanding to us and Hain Celestial, and we and Hain Celestial are entitled to interest receivables of \$80,000 each.

## Agreements with Our Directors and Executive Officers

## Director and Executive Officer Compensation

See Item 6.B. "Compensation—Executive Officer Compensation" and "Compensation—Director Compensation" for a discussion of our compensation of directors and executive officers.

## **Equity Compensation**

See Item 6.B. "Compensation—Equity Compensation Schemes and Other Benefit Plans."

## **Employment Agreements**

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see Item 6.B. "Compensation—Employment Arrangements with our Executive Officers."

### Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. We also maintain a general liability insurance policy which covers certain liabilities of our directors and executive officers arising out of claims based on acts or omissions in their capabilities as directors or officers.

### C. Interests of Experts and Counsel

Not applicable.

## ITEM 8. FINANCIAL INFORMATION

## A. Consolidated Financial Statements and Other Financial Information.

See Item 18 "Financial Statements."

## A.7 Legal Proceedings

There are no material legal proceedings pending or, to our knowledge, threatened against us. From time to time we become subject to legal proceedings and claims in the ordinary course of our business, including claims of alleged infringement of patents and other intellectual property rights. Such legal proceedings or claims, even if not meritorious, could result in the expenditure of significant financial and management resources.

## A.8 Dividend Policy

We have never declared or paid dividends on our ordinary shares. We currently expect to retain all future earnings for use in the operation and expansion of our business and do not have any present plan to pay any dividends. The declaration and payment of any dividends in the future will be determined by our board of directors in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions.

## 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

Not applicable except for Item 9.A.4 and Item 9.C.

Our ADSs have been listed on the Nasdaq Global Select Market since March 17, 2016 under the symbol "HCM." The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on the Nasdaq Global Select Market in U.S. dollars.

	 Price Per ADS		
	 High		Low
Annual:			
2016 (since March 17, 2016)	\$ 14.94	\$	11.26
2017	\$ 39.42	\$	12.74
2018 (through March 1, 2018)	\$ 41.14	\$	30.62
Quarterly:			
First Quarter 2016 (since March 17, 2016)	\$ 13.50	\$	13.20
Second Quarter 2016	\$ 14.18	\$	12.32
Third Quarter 2016	\$ 13.76	\$	11.90
Fourth Quarter 2016	\$ 14.94	\$	11.26
First Quarter 2017	\$ 20.57	\$	12.74
Second Quarter 2017	\$ 23.69	\$	18.30
Third Quarter 2017	\$ 27.50	\$	22.15
Fourth Quarter 2017	\$ 39.42	\$	27.41
First Quarter 2018 (through March 1, 2018)	\$ 41.14	\$	30.62
Most Recent Six Months:			
September 2017	\$ 27.27	\$	25.02
October 2017	\$ 31.74	\$	27.41
November 2017	\$ 35.42	\$	29.49
December 2017	\$ 39.42	\$	30.26
January 2018	\$ 41.14	\$	36.01
February 2018	\$ 37.08	\$	30.62
March 2018 (through March 1, 2018)	\$ 34.80	\$	34.80

Our ordinary shares have been listed on the AIM market of the London Stock Exchange since May 19, 2006. The following table sets forth, for the periods indicated, the reported high and low closing

sale prices of our ordinary shares on the AIM in pounds sterling and U.S. dollars. U.S. dollar per ordinary share amounts have been translated into U.S. dollars at £1.00=\$1.34.

	Price Per Ordinary Share			Ordinary are
	High	Low	High	Low
Annual:				
2013	£ 6.39	£ 4.15	\$ 8.56	\$ 5.56
2014	£ 15.30	£ 6.21	\$ 20.50	\$ 8.32
2015	£ 28.35	£ 11.80	\$ 37.99	\$ 15.81
2016	£ 27.90	£ 16.85	\$ 37.39	\$ 22.58
2017	£ $56.00$	£ 20.82	\$ 75.04	\$ 27.90
2018 (through March 1, 2018)	£ 59.00	£ 43.05	\$ 79.06	\$ 57.69
Quarterly:				
First Quarter 2016	£ 27.90	£ 18.50	\$ 37.39	\$ 24.79
Second Quarter 2016	£ $24.08$	£ 16.80	\$ 32.27	\$ 22.51
Third Quarter 2016	£ 19.58	£ 17.88	\$ 26.24	\$ 23.96
Fourth Quarter 2016	£ 23.70	£ 17.85	\$ 31.76	\$ 23.92
First Quarter 2017	£ 32.53	£ 20.82	\$ 43.59	\$ 27.90
Second Quarter 2017	£ 36.58	£ 29.10	\$ 49.02	\$ 38.99
Third Quarter 2017	£ 40.50	£ 33.88	\$ 54.27	\$ 45.40
Fourth Quarter 2017	£ $56.00$	£ 40.18	\$ 75.04	\$ 53.84
First Quarter 2018 (through March 1, 2018)	£ 59.00	£ 43.05	\$ 79.06	\$ 57.69
Most Recent Six Months:				
September 2017	£ 40.25	£ 36.48	\$ 53.94	\$ 48.88
October 2017	£ 48.13	£ 40.18	\$ 64.49	\$ 53.84
November 2017	£ 52.63	£ 44.95	\$ 70.52	\$ 60.23
December 2017	£ $56.00$	£ 46.13	\$ 75.04	\$ 61.81
January 2018	£ 59.00	£ 50.80	\$ 79.06	\$ 68.07
February 2018	£ 51.80	£ 43.05	\$ 69.41	\$ 57.69
March 2018 (through March 1, 2018)	£ 47.75	£ 47.75	\$ 63.99	\$ 63.99

## ITEM 10. ADDITIONAL INFORMATION

## A. Share Capital.

Not applicable.

## B. Memorandum and Articles of Association.

The information contained under the caption of "Our Memorandum and Articles of Association" in the Company's Registration Statement on Form F-1 filed March 4, 2016 (file number 333-207447) is incorporated herein by reference.

#### C. Material Contracts.

Except as otherwise disclosed in this annual report (including the exhibits hereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of our business.

### D. Exchange Controls.

Foreign currency exchange in the PRC is primarily governed by the Foreign Exchange Administration Rules issued by the State Council on January 29, 1996 and effective as of April 1, 1996 (and amended on

January 14, 1997 and August 1, 2008) and the Regulations of Settlement, Sale and Payment of Foreign Exchange which came into effect on July 1, 1996.

Under the Foreign Exchange Administration Rules, renminbi is freely convertible for current account items, including the distribution of dividends payments, interest payments, trade and service-related foreign exchange transactions. Conversion of renminbi for capital account items, such as direct investment, loans, securities investment and repatriation of investment, however, is still generally subject to the approval or verification of SAFE.

Under the Regulations of Settlement, Sale and Payment of Foreign Exchange, foreign invested enterprises including wholly foreign owned enterprises, may buy, sell or remit foreign currencies only at those banks that are authorized to conduct foreign exchange business after providing such banks with valid commercial supporting documents and, in the case of capital account item transactions, after obtaining approvals from SAFE. Capital investments by foreign invested enterprises outside the PRC are also subject to limitations, which include approvals by the MOFCOM, the SAFE and the NDRC.

In March 2015, SAFE released the Circular on Reforming the Management Approach regarding the Foreign Exchange Capital Settlement of Foreign-invested Enterprises, or FIEs, or the Foreign Exchange Capital Settlement Circular, which became effective from June 1, 2015. This circular replaced SAFE's previous related circulars, including the Circular on Issues Relating to the Improvement of Business Operation with Respect to the Administration of Foreign Exchange Capital Payment and Settlement of Foreign Invested Enterprises. The Foreign Exchange Capital Settlement Circular clarifies that FIEs may settle a specified proportion of their foreign exchange capital in banks at their discretion, and may choose the timing for such settlement. The proportion of foreign exchange capital to be settled at FIEs' discretion for the time being is 100% and the SAFE may adjust the proportion in due time based on the situation of international balance of payments. The circular also stipulates that FIEs' usage of capital and settled foreign exchange capital shall comply with relevant provisions concerning foreign exchange control and be subject to the management of a negative list. The FIEs' capital and Renminbi capital gained from the settlement of foreign exchange capital may not be directly or indirectly used for expenditure beyond the business scope of the FIEs or as prohibited by laws and regulations of the PRC. Such capital also may not be directly or indirectly used for issuing renminbi entrusted loans except as permitted by the business scope of the FIE, for repaying inter-enterprise borrowings including any third-party advance, or for repaying the bank loans denominated in renminbi that have been sub-lent to a third party.

In addition, the payment of dividends by entities established in the PRC is subject to limitations. Regulations in the PRC currently permit payment of dividends only out of accumulated profits as determined in accordance with accounting standards and regulations in the PRC. Each of our PRC subsidiaries and joint ventures that is a domestic company is also required to set aside at least 10.0% of its after-tax profit based on PRC accounting standards each year to its general reserves or statutory capital reserve fund until the accumulative amount of such reserves reach 50.0% of its respective registered capital. These restricted reserves are not distributable as cash dividends. In addition, if any of our PRC subsidiaries or joint ventures incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us.

For more information about foreign exchange control, see Item 3.D. "Risk Factors—Risks Related to Doing Business in China—Restrictions on currency exchange may limit our ability to utilize our revenues effectively."

## E. Taxation

The following is a general summary of certain PRC, Hong Kong, Cayman Islands and U.S. federal income tax consequences relevant to the acquisition, ownership and disposition of our ADSs. The discussion is not intended to be, nor should it be construed as, legal or tax advice to any particular individual. The discussion is based on laws and relevant interpretations thereof in effect as of March 1,

2018, all of which are subject to change or different interpretations, possibly with retroactive effect. The discussion does not address U.S. state or local tax laws, or tax laws of jurisdictions other than the PRC, Hong Kong, the Cayman Islands, the United Kingdom and the United States. You should consult your own tax advisors with respect to the consequences of acquisition, ownership and disposition of our ADSs and ordinary shares.

#### Taxation in the PRC

## PRC Enterprise Income Tax

Under the EIT Law and its implementation rules which became effective on January 1, 2008 and was later amended on February 24, 2017, the standard tax rate of 25% applies to all enterprises (including FIEs) with exceptions in special situations if relevant criteria are met and subject to the approval of the PRC tax authorities.

An enterprise incorporated outside of the PRC whose "de facto management bodies" are located in the PRC is considered a "resident enterprise" and will be subject to a uniform EIT rate of 25% on its global income. In April 2009, the SAT, in Circular 82, specified certain criteria for the determination of what constitutes "de facto management bodies." If all of these criteria are met, the relevant foreign enterprise will be deemed to have its "de facto management bodies" located in the PRC and therefore be considered a resident enterprise in the PRC. These criteria include: (a) the enterprise's day-to-day operational management is primarily exercised in the PRC; (b) decisions relating to the enterprise's financial and human resource matters are made or subject to approval by organizations or personnel in the PRC; (c) the enterprise's primary assets, accounting books and records, company seals, and board and shareholders' meeting minutes are located or maintained in the PRC; and (d) 50% or more of voting board members or senior executives of the enterprise habitually reside in the PRC. In addition, an enterprise established outside the PRC which meets all of the aforesaid requirements is expected to make an application for the classification as a "resident enterprise" and this will ultimately be confirmed by the province-level tax authority. Although Circular 82 only applies to foreign enterprises that are majorityowned and controlled by PRC enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in Circular 82 may be adopted by the PRC tax authorities as the test for determining whether the enterprises are PRC tax residents, regardless of whether they are majority-owned and controlled by PRC enterprises. However, it is not entirely clear how the PRC tax authorities will determine whether a non-PRC entity (that has not already been notified of its status for EIT purposes) will be classified as a "resident enterprise" in practice.

Except for our PRC subsidiaries and joint ventures incorporated in China, we believe that none of our entities incorporated outside of China is a PRC resident enterprise for PRC tax purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities, and uncertainties remain with respect to the interpretation of the term "de facto management body."

If a non-PRC enterprise is classified as a "resident enterprise" for EIT purposes, any dividends to be distributed by that enterprise to non-PRC resident shareholders or ADS holders or any gains realized by such investors from the transfer of shares or ADSs may be subject to PRC tax. If the PRC tax authorities determine that we should be considered a PRC resident enterprise for EIT purposes, any dividends payable by us to our non-PRC resident enterprise shareholders or ADS holders, as well as gains realized by such investors from the transfer of our shares or ADSs may be subject to a 10% withholding tax, unless a reduced rate is available under an applicable tax treaty. Furthermore, if we are considered a PRC resident enterprise for EIT purposes, it is unclear whether our non-PRC individual shareholders (including our ADS holders) would be subject to any PRC tax on dividends or gains obtained by such non-PRC individual shareholders. If any PRC tax were to apply to dividends realized by non-PRC individuals, it would generally apply at a rate of up to 20% unless a reduced rate is available under an applicable tax treaty.

According to the EIT Law, dividends declared after January 1, 2008 and paid by PRC FIEs to their non-PRC parent companies will be subject to PRC withholding tax at 10% unless there is a tax treaty between the PRC and the jurisdiction in which the overseas parent company is a tax resident and which specifically exempts or reduces such withholding tax, and such tax exemption or reduction is approved by the relevant PRC tax authorities. Pursuant to the Arrangement, if the non-PRC immediate holding company is a Hong Kong tax resident and directly holds a 25% or more equity interest in the PRC enterprise and is considered to be the beneficial owner of dividends paid by the PRC enterprise, such withholding tax rate may be lowered to 5%, subject to approval by the relevant PRC tax authorities in accordance with relevant tax regulations upon the assessment of beneficial ownership.

#### Business Tax

A business which provides certain services or sells/transfers immovable or intangible property within the PRC (including when either party of a transaction is within the PRC unless in specified situations) was liable to Business Tax at rates ranging from 3% to 20% of the charges for the services provided or immovable or intangible property sold or transferred (as the case may be). The Business Tax rate of 3% was applicable on taxable services relating to construction, culture and sports. All other services generally attracted a Business Tax rate of 5%, except that services relating to entertainment are subject to a rate ranging from 5% to 20%.

In addition, Business Tax was payable on the gross amount of all billings unless specific rules stipulated the use of a net amount.

A Municipal Maintenance Tax, together with an Education Surcharge and a Local Education Surcharge, were payable at a rate, in aggregate, of 6% to 12% of the Business Tax.

The Business Tax regime has been replaced in full with effect from 1 May 2016, as described in the section below on Value Added Tax, or VAT.

#### Value Added Tax

The Interim Regulations of the PRC on VAT, or the VAT Regulations, came into effect on January 1, 2009 (subsequently amended on February 6, 2016 and November 19, 2017). Pursuant to the VAT Regulations, VAT is imposed on the goods sold in or imported into the PRC and on processing, repair and replacement services provided within the PRC.

The pilot program of the PRC indirect tax reform was first implemented in Shanghai, the PRC, effective from January 1, 2012 where certain industries are transformed from the Business Tax regime to the VAT regime. The program was expanded in stages.

The MOF, and the SAT jointly promulgated the Circular on Comprehensively Promoting the Pilot Program of the Collection of VAT in Lieu of Business Tax, or the 2016 VAT Circular, on 23 March 2016, which came into effect on 1 May 2016. Pursuant to the 2016 VAT Circular, the sale of services, intangible assets or real property within the PRC (including when either party of a transaction is within the PRC unless in specified situations) is subject to VAT instead of Business Tax, with VAT rates being 6%, 11% or 17%, while the VAT rate could be zero for certain specified cross-border taxable items/services, in accordance with the relevant regulations.

A Municipal Maintenance Tax, together with Education Surcharge and a Local Education Surcharge, are payable at a rate, in aggregate, of 6% to 12% of the VAT.

## Land Appreciation Tax

Some of our PRC subsidiaries and joint ventures have obtained certain land use rights and ownership in buildings.

Under the Provisional Regulations of the PRC on Land Appreciation Tax, or LAT, promulgated by the State Council on December 13, 1993 (which became effective on January 1, 1994) and amended on January 8, 2011, together with its implementing rules which were promulgated by the MOF on January 27, 1995, LAT applies to both domestic and foreign investors in real properties in the PRC, irrespective of corporate entities or individuals. The tax is payable by a taxpayer on the gains from the transfer of land use right, buildings or other facilities on such land, after deducting "deductible items" that include: (a) payments made to acquire land use right; (b) costs and charges incurred in connection with land development; (c) construction costs and charges in the case of newly constructed buildings and facilities; (d) assessed value in the case of old buildings and facilities; (f) taxes paid or payable in connection with the transfer of the land use right, buildings or other facilities on such land; and (e) other items allowed by the MOF.

The tax rate is progressive and ranges from 30% to 60% of the appreciation value, as follows:

Appreciation Value	LAT Rate
Portion not exceeding 50% of deductible items:	30%
Portion over 50% but not more than 100% of deductible items:	40%
Portion over 100% but not more than 200% of deductible items:	50%
Portion over 200% of deductible items:	60%

Exemption from LAT is available under certain specified situations.

### Deed Tax

Pursuant to the Provisional Regulations of the PRC on Deed Tax promulgated by the State Council on July 7, 1997 and implemented on October 1, 1997, the transferee of the land use right and/or property ownership in the PRC will be the obliged taxpayer for Deed Tax. The rate of Deed Tax ranges from 3% to 5%, subject to determination by local governments at the provincial level in light of local conditions.

#### Real Estate Tax

Properties owned by an enterprise will be subject to Real Estate Tax at variable rates depending on locality. In certain localities, Real Estate Tax is applicable at a rate of 1.2% of the original value of the building less a standard deduction which ranges from 10% to 30% of the original value or at a rate of 12% of the rental income.

#### Urban Land Use Tax

According to the Provisional Regulations on Urban Land Use Tax of the PRC promulgated by the State Council in September 1988 and amended in December 2006 and December 2013, Urban Land Use Tax is levied according to the area of relevant land, at between RMB0.6 and RMB30 per square meter.

#### Stamp Duty

According to the Provisional Regulations of the PRC on Stamp Duty promulgated by the State Council in August 1988 and amended on January 8, 2011, specified documents primarily business contracts are subject to Stamp Duty at the specified rates on the amount stated therein, including but not limited to: purchase and sales agreements—0.03%; loan agreements—0.005%; assets transfer agreements—0.05%. Such Stamp Duty is payable by every party to a contract.

#### Overview of Tax Implications of Various Other Jurisdictions

#### Cayman Islands Taxation

According to our Cayman Islands counsel, Conyers Dill & Pearman, the Cayman Islands currently levies 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. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or brought within the jurisdiction of the Cayman Islands. The Cayman Islands is a party to a double tax treaty entered into with the United Kingdom in 2010 but it is otherwise not a party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Pursuant to the Tax Concessions Law (1999 Revision) of the Cayman Islands, Hutchison China MediTech Limited has obtained an undertaking from the Governor-in-Council: (a) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits or income or gains or appreciations shall apply to us or our operations; and (b) that the aforesaid tax or any tax in the nature of estate duty or inheritance tax shall not be payable on its shares, debentures or other obligations.

The undertaking is for a period of twenty years from January 9, 2001.

Hong Kong Taxation

#### **Profits Tax**

Hong Kong tax residents are subject to Hong Kong Profits Tax in respect of profits arising in or derived from Hong Kong at the current rate of 16.5%. Dividend income earned by a Hong Kong tax resident is not subject to Hong Kong Profits Tax. Hutchison China MediTech Limited is a Hong Kong tax resident.

## Hong Kong tax on shareholders and ADS holders

No tax is payable in Hong Kong in respect of dividends paid by a Hong Kong tax resident to their shareholders, including our ADS holders.

Hong Kong Profits Tax will not be payable by our shareholders, including our ADS holders (other than shareholders / ADS holders carrying on a trade, profession or business in Hong Kong and holding the shares / ADSs for trading purposes), on any capital gains made on the sale or other disposal of the ADSs. Shareholders, including our ADS holders, should take advice from their own professional advisors as to their particular tax position.

No Hong Kong Stamp Duty is payable by our shareholders, including our ADS holders.

#### Material U.S. Federal Income Tax Considerations

The following summary, subject to the limitations set forth below, describes the material U.S. federal income tax consequences for a U.S. Holder (as defined below) of the acquisition, ownership and disposition of ordinary shares and ADSs. This discussion is limited to U.S. Holders who hold such ordinary shares or ADSs as capital assets (generally, property held for investment). For purposes of this summary, a "U.S. Holder" is a beneficial owner of an ordinary share or ADS that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) organized in or under the laws of the United States or any state thereof, or the District of Columbia;

- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) it has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes or (ii) a U.S. court can exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions.

Except as explicitly set forth below, this summary does not address aspects of U.S. federal income taxation that may be applicable to U.S. Holders subject to special rules, including:

- banks or other financial institutions;
- insurance companies;
- real estate investment trusts;
- regulated investment companies;
- grantor trusts;
- tax-exempt organizations;
- persons holding our ordinary shares or ADSs through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- dealers or traders in securities, commodities or currencies;
- persons whose functional currency is not the U.S. dollar;
- certain former citizens and former long-term residents of the United States;
- persons holding our ordinary shares or ADSs as part of a position in a straddle or as part of a hedging, conversion or integrated transaction for U.S. federal income tax purposes; or
- direct, indirect or constructive owners of 10% or more of our equity (by vote or value).

In addition, this summary does not address the 3.8% Medicare contribution tax imposed on certain net investment income, the U.S. federal estate and gift tax or the alternative minimum tax consequences of the acquisition, ownership, and disposition of our ordinary shares or ADSs. We have not received nor do we expect to seek a ruling from the U.S. Internal Revenue Service, or the IRS, regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of our ordinary shares and ADSs.

This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between the PRC and the United States, or the U.S.-PRC Tax Treaty, each as available and in effect on the date hereof, all of which are subject to change or differing interpretations, possibly with retroactive effect, which could affect the tax consequences described herein. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership should consult its own tax advisors as to the U.S. federal income tax consequences of acquiring, owning and disposing of our ordinary shares or ADSs.

PROSPECTIVE INVESTORS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH REGARD TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEIR SITUATIONS AS WELL AS THE APPLICATION OF ANY U.S. FEDERAL, STATE, LOCAL, NON-U.S. OR OTHER TAX LAWS, INCLUDING GIFT AND ESTATE TAX LAWS.

**ADSs** 

A U.S. Holder of ADSs will generally be treated, for U.S. federal income tax purposes, as the owner of the underlying ordinary shares that such ADSs represent. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs for the underlying shares represented by those ADSs.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depositary or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. Holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate U.S. Holders. Accordingly, the creditability of non-U.S. withholding taxes (if any), and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries. For purposes of the discussion below, we assume that intermediaries in the chain of ownership between the holder of an ADS and us are acting consistently with the claim of U.S. foreign tax credits by U.S. Holders.

## Taxation of Dividends

As described in "Dividend Policy" above, we do not currently anticipate paying any distributions on our ordinary shares or ADSs in the foreseeable future. However, to the extent there are any distributions made with respect to our ordinary shares or ADSs, and subject to the discussion under "—Passive Foreign Investment Company Considerations" below, the gross amount of any such distribution (including withheld taxes, if any) made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually or constructively received. Distributions in excess of our current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in the ordinary shares or ADSs, as applicable, and thereafter as capital gain. However, because we do not maintain calculations of our earnings and profits in accordance with U.S. federal income tax accounting principles, U.S. Holders should expect to treat distributions paid with respect to our ordinary shares and ADSs as dividends. Dividends paid to corporate U.S. Holders generally will not qualify for the dividends received deduction that may otherwise be allowed under the Code. This discussion assumes that distributions made by us, if any, will be paid in U.S. dollars.

Dividends paid to a non-corporate U.S. Holder by a "qualified foreign corporation" may be subject to reduced rates of U.S. federal income taxation if certain holding period and other requirements are met. A qualified foreign corporation generally includes a foreign corporation (other than a PFIC) if (1) its ordinary shares (or ADSs backed by ordinary shares) are readily tradable on an established securities market in the United States or (2) it is eligible for benefits under a comprehensive U.S. income tax treaty that includes an exchange of information program and which the U.S. Treasury Department has determined is satisfactory for these purposes.

IRS guidance indicates that our ADSs (which are listed on the Nasdaq Global Select Market) are readily tradable for purposes of satisfying the conditions required for these reduced tax rates. We do not expect, however, that our ordinary shares will be listed on an established securities market in the United States and therefore do not believe that any dividends paid on our ordinary shares that are not represented by ADSs currently meet the conditions required for these reduced tax rates. There can be no assurance that our ADSs will be considered readily tradable on an established securities market in subsequent years.

The United States does not have a comprehensive income tax treaty with the Cayman Islands. However, in the event that we were deemed to be a PRC resident enterprise under the EIT Law (see "—Taxation in the PRC" above), although no assurance can be given, we might be considered eligible for the benefits of the U.S.-PRC Tax Treaty for purposes of these rules. U.S. Holders should consult their own

tax advisors regarding the availability of the reduced tax rates on dividends paid with respect to our ordinary shares or ADSs in light of their particular circumstances.

Non-corporate U.S. Holders will not be eligible for reduced rates of U.S. federal income taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year unless, under certain circumstances, the "deemed sale election" described below under "—Passive Foreign Investment Company Considerations—Status as a PFIC" has been made.

In the event that we were deemed to be a PRC resident enterprise under the EIT Law (see "—Taxation in the PRC" above), U.S. Holders might be subject to PRC withholding taxes on dividends paid by us. In that case, subject to certain conditions and limitations, such PRC withholding tax may be treated as a foreign tax eligible for credit against a U.S. Holder's U.S. federal income tax liability under the U.S. foreign tax credit rules. For purposes of calculating the U.S. foreign tax credit, dividends paid on our ordinary shares or ADSs, will be treated as income from sources outside the United States and will generally constitute passive category income. If a U.S. Holder is eligible for U.S.-PRC Tax Treaty benefits, any PRC taxes on dividends will not be creditable against such U.S. Holder's U.S. federal income tax liability to the extent such tax is withheld at a rate exceeding the applicable U.S.-PRC Tax Treaty rate. An eligible U.S. Holder who does not elect to claim a foreign tax credit for PRC tax withheld may instead be eligible to claim a deduction, for U.S. federal income tax purposes, in respect of such withholding but only for the year in which such U.S. Holder elects to do so for all creditable foreign income taxes. The U.S. foreign tax credit rules are complex. U.S. Holders should consult their own tax advisors regarding the foreign tax credit rules in light of their particular circumstances.

## Taxation of Capital Gains

Subject to the discussion below in "—Passive Foreign Investment Company Considerations," upon the sale, exchange, or other taxable disposition of our ordinary shares or ADSs, a U.S. Holder generally will recognize gain or loss in an amount equal to the difference between the amount realized on such sale or exchange (determined in the case of sales or exchanges in currencies other than U.S. dollars by reference to the spot exchange rate in effect on the date of the sale or exchange or, if sold or exchanged on an established securities market and the U.S. Holder is a cash basis taxpayer or an electing accrual basis taxpayer, the spot exchange rate in effect on the settlement date) and the U.S. Holder's adjusted tax basis in such ordinary shares or ADSs determined in U.S. dollars. A U.S. Holder's initial tax basis will be the U.S. Holder's U.S. dollar purchase price for such ordinary shares or ADSs.

Assuming we are not a PFIC and have not been treated as a PFIC during the U.S. Holder's holding period for its ordinary shares or ADSs, such gain or loss will be capital gain or loss. Under current law, capital gains of non-corporate U.S. Holders derived with respect to capital assets held for more than one year are generally eligible for reduced rates of taxation. The deductibility of capital losses is subject to limitations. Capital gain or loss, if any, recognized by a U.S. Holder generally will be treated as U.S. source income or loss for U.S. foreign tax credit purposes. U.S. Holders are encouraged to consult their own tax advisors regarding the availability of the U.S. foreign tax credit in consideration of their particular circumstances.

If we were treated as a PRC resident enterprise for EIT Law purposes and PRC tax were imposed on any gain (see "—Taxation in the PRC" above), and if a U.S. Holder is eligible for the benefits of the U.S.-PRC Tax Treaty, the holder may be able to treat such gain as PRC source gain under the treaty for U.S. foreign tax credit purposes. A U.S. Holder will be eligible for U.S.-PRC Tax Treaty benefits if (for purposes of the treaty) such holder is a resident of the United States and satisfies the other requirements specified in the U.S.-PRC Tax Treaty. Because the determination of treaty benefit eligibility is fact-intensive and depends upon a holder's particular circumstances, U.S. Holders should consult their tax advisors regarding U.S.-PRC Tax Treaty benefit eligibility. U.S. Holders are also encouraged to consult their own tax advisors regarding the tax consequences in the event PRC tax were to be imposed on a

disposition of ordinary shares or ADSs, including the availability of the U.S. foreign tax credit and the ability and whether to treat any gain as PRC source gain for the purposes of the U.S. foreign tax credit in consideration of their particular circumstances.

Passive Foreign Investment Company Considerations

#### Status as a PFIC

The rules governing PFICs can result in adverse tax consequences to U.S. Holders. We generally will be classified as a PFIC for U.S. federal income tax purposes if, for any taxable year, either: (1) 75% or more of our gross income consists of certain types of passive income, or (2) the average value (determined on a quarterly basis), of our assets that produce, or are held for the production of, passive income is 50% or more of the value of all of our assets.

Passive income generally includes dividends, interest, rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from assets that produce passive income. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. Under this rule, we should be deemed to own a proportionate share of the assets and to have received a proportionate share of the income of our principal subsidiaries, including Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited, Shanghai Hutchison Pharmaceuticals Limited and Nutrition Science Partners Limited, for purpose of the PFIC determination.

Additionally, if we are classified as a PFIC in any taxable year with respect to which a U.S. Holder owns ordinary shares or ADSs, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to meet the tests described above, unless the U.S. Holder makes the "deemed sale election" described below. Furthermore, if we are treated as a PFIC, then one or more of our subsidiaries may also be treated as PFICs.

Based on certain estimates of our gross income and gross assets (which estimates are inherently imprecise) and the nature of our business, we do not believe that we are currently a PFIC. Notwithstanding the foregoing, the determination of whether we are a PFIC is made annually and depends on particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and also may be affected by the application of the PFIC rules, which are subject to differing interpretations. The fair market value of our assets is expected to depend, in part, upon (a) the market price of our ADSs, which is likely to fluctuate, and (b) the composition of our income and assets, which will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. In light of the foregoing, no assurance can be provided that we are not currently a PFIC or that we will not become a PFIC in any future taxable year. Prospective investors should consult their own tax advisors regarding our PFIC status.

## U.S. federal income tax treatment of a shareholder of a PFIC

If we are classified as a PFIC for any taxable year during which a U.S. Holder owns ordinary shares or ADSs, the U.S. Holder, absent certain elections (including the mark-to-market and QEF elections described below), generally will be subject to adverse rules (regardless of whether we continue to be classified as a PFIC) with respect to (1) any "excess distributions" (generally, any distributions received by the U.S. Holder on its ordinary shares or ADSs in a taxable year that are greater than 125% of the average annual distributions received by the U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period) and (2) any gain realized on the sale or other disposition, including a pledge, of such ordinary shares or ADSs.

Under these rules (a) the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period, (b) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we are classified as a PFIC will be taxed as ordinary income and (c) the amount allocated to each other taxable year during the U.S. Holder's holding period in which we were classified as a PFIC (i) will be subject to tax at the highest rate of tax in effect for the applicable category of taxpayer for that year and (ii) will be subject to an interest charge at a statutory rate with respect to the resulting tax attributable to each such other taxable year. In addition, non-corporate U.S. Holders will not be eligible for reduced rates of taxation on any dividends received from us if we are a PFIC in the taxable year in which such dividends are paid or in the preceding taxable year.

If we are classified as a PFIC, a U.S. Holder will generally be treated as owning a proportionate amount (by value) of stock or shares owned by us in any direct or indirect subsidiaries that are also PFICs and will be subject to similar adverse rules with respect to any distributions we receive from, and dispositions we make of, the stock or shares of such subsidiaries. U.S. Holders are urged to consult their tax advisors about the application of the PFIC rules to any of our subsidiaries.

If we are classified as a PFIC and then cease to be so classified, a U.S. Holder may make an election (a "deemed sale election") to be treated for U.S. federal income tax purposes as having sold such U.S. Holder's ordinary shares or ADSs on the last day of our taxable year during which we were a PFIC. A U.S. Holder that makes a deemed sale election would then cease to be treated as owning stock in a PFIC. However, gain recognized as a result of making the deemed sale election would be subject to the adverse rules described above and loss would not be recognized.

#### PFIC "mark-to-market" election

In certain circumstances, a holder of "marketable stock" of a PFIC can avoid certain of the adverse rules described above by making a mark-to-market election with respect to such stock. For purposes of these rules "marketable stock" is stock which is "regularly traded" (traded in greater than de minimis quantities on at least 15 days during each calendar quarter) on a "qualified exchange" or other market within the meaning of applicable U.S. Treasury Regulations. A "qualified exchange" includes a national securities exchange that is registered with the SEC.

A U.S. Holder that makes a mark-to-market election must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the U.S. Holder's ordinary shares or ADSs that are "marketable stock" at the close of the taxable year over the U.S. Holder's adjusted tax basis in such ordinary shares or ADSs. An electing U.S. Holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted tax basis in such ordinary shares or ADSs over their fair market value at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains previously included in income pursuant to the mark-to-market election. The adjusted tax basis of a U.S. Holder's ordinary shares or ADSs with respect to which the mark-to-market election applies would be adjusted to reflect amounts included in gross income or allowed as a deduction because of such election. If a U.S. Holder makes an effective mark-to-market election with respect to our ordinary shares or ADSs, gains from an actual sale or other disposition of such ordinary shares or ADSs in a year in which we are a PFIC would be treated as ordinary income, and any losses incurred on such sale or other disposition would be treated as ordinary losses to the extent of any net mark-to-market gains previously included in income.

If we are classified as a PFIC for any taxable year in which a U.S. Holder owns ordinary shares or ADSs but before a mark-to-market election is made, the adverse PFIC rules described above will apply to any mark-to-market gain recognized in the year the election is made. Otherwise, a mark-to-market election will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ordinary shares or ADSs are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election. Our ADSs are listed on the Nasdaq Global Select Market, which is a

qualified exchange or other market for purposes of the mark-to-market election. Consequently, if the ADSs continue to be so listed, and are "regularly traded" for purposes of these rules (for which no assurance can be given) we expect that the mark-to-market election would be available to a U.S. Holder with respect to our ADSs.

A mark-to-market election is not permitted for the shares of any of our subsidiaries that are also classified as PFICs. Prospective investors should consult their own tax advisors regarding the availability of, and the procedure for, and the effect of making, a mark-to-market election, and whether making the election would be advisable, including in light of their particular circumstances.

### PFIC "QEF" election

In some cases, a shareholder of a PFIC can avoid the interest charge and the other adverse PFIC tax consequences described above by obtaining certain information from the PFIC and by making a QEF election to be taxed currently on its share of the PFIC's undistributed income. We do not, however, expect to provide the information regarding our income that would be necessary in order for a U.S. Holder to make a QEF election if we were classified as a PFIC.

## PFIC information reporting requirements

If we are classified as a PFIC in any year with respect to a U.S. Holder, such U.S. Holder will be required to file an annual information return on IRS Form 8621 regarding distributions received on, and any gain realized on the disposition of, our ordinary shares and ADSs, and certain U.S. Holders will be required to file an annual information return (also on IRS Form 8621) relating to their ownership interest.

NO ASSURANCE CAN BE GIVEN THAT WE ARE NOT CURRENTLY A PFIC OR THAT WE WILL NOT BECOME A PFIC IN THE FUTURE. U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE OPERATION OF THE PFIC RULES AND RELATED REPORTING REQUIREMENTS IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES, INCLUDING THE ADVISABILITY AND EFFECTS OF MAKING ANY ELECTION THAT MAY BE AVAILABLE.

#### U.S. Backup Withholding and Information Reporting and Filing Requirements

Backup withholding and information reporting requirements may apply to distributions on, and proceeds from the sale or disposition of, ordinary shares and ADSs that are held by U.S. Holders. The payor will be required to withhold tax on such payments made within the United States, or by a U.S. payor or a U.S. intermediary (and certain subsidiaries thereof) to a U.S. Holder, other than an exempt recipient, if the U.S. Holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding requirements. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder's U.S. federal income tax liability (if any) or refunded provided the required information is furnished to the IRS in a timely manner.

Certain U.S. Holders of specified foreign financial assets with an aggregate value in excess of the applicable dollar threshold are required to report information relating to their holding of ordinary shares or ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by certain financial institutions) with their tax returns for each year in which they hold such interests. U.S. Holders should consult their own tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of our ordinary shares or ADSs.

THE ABOVE DISCUSSION DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. PROSPECTIVE INVESTORS ARE STRONGLY

URGED TO CONSULT THEIR OWN TAX ADVISORS ABOUT THE TAX CONSEQUENCES OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs.

# F. Dividends and Payment Agents.

Not applicable.

## G. Statement by Experts.

Not applicable.

#### H. Documents on Display.

We are subject to the informational requirements of the Exchange Act and are required to file reports and other information with the SEC. Shareholders may read and copy any of our reports and other information at, and obtain copies upon payment of prescribed fees from, the public reference room maintained by the SEC at 100 F Street N.E., Washington, D.C. 20549. The public may obtain information on the operation of the public reference room by calling the U.S. Securities and Exchange Commission at 1-800-SEC-0330. The SEC also maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system.

We are a "foreign private issuer" as such term is defined in Rule 405 under the Securities Act, and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. As a result, we do not file the same reports that a U.S. domestic issuer would file with the SEC, although we are required to file or furnish to the SEC the continuous disclosure documents that we are required to file on the AIM market of the London Stock Exchange.

We will furnish Deutsche Bank Trust Company Americas, the depositary of our ADSs, with our annual reports, which will include a review of operation and annual audited consolidated financial statements prepared in conformity with U.S. GAAP, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depositary will make such notices, reports and communications available to holders of ADSs and, upon our requests, will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depositary from us.

We also make available on our website's investor relations page, free of charge, our annual report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. The address for our investor relations page is "http://www.chi-med.com/investors/." The information contained on our website is not incorporated by reference in this annual report.

#### I. Subsidiary information

Not applicable.

## ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Please see Item 5.F. "Operating and Financial Review and Prospects—Quantitative and Qualitative Disclosures About Market Risk."

## 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.

## D. American Depositary Shares.

## Fees and charges our ADS holders may have to pay

ADS holders will be required to pay the following service fees to Deutsche Bank Trust Company America, the depositary of our ADS program, and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by ADSs):

Service	Fees
• To any person to which ADSs are issued or to any person to which a distribution is made in respect of ADS distributions pursuant to stock dividends or other free distributions of stock, bonus distributions, stock splits or other distributions (except where converted to cash)	Up to \$0.05 per ADS issued
<ul> <li>Cancellation or withdrawal of ADSs, including the case of termination of the deposit agreement</li> </ul>	Up to \$0.05 per ADS cancelled
• Distribution of cash dividends	Up to \$0.05 per ADS held
<ul> <li>Distribution of cash entitlements (other than cash dividends) and/or cash proceeds from the sale of rights, securities and other entitlements</li> </ul>	Up to \$0.05 per ADS held
• Distribution of ADSs pursuant to exercise of rights	Up to \$0.05 per ADS held
Depositary services	Up to \$0.05 per ADS held on the applicable record date(s) established by the depositary bank (an annual fee)

ADS holders will also be responsible to pay certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of your ADSs) such as:

- Fees for the transfer and registration of ordinary shares charged by the registrar and transfer agent for the ordinary shares in the Cayman Islands (i.e., upon deposit and withdrawal of ordinary shares).
- Expenses incurred for converting foreign currency into U.S. dollars.
- Expenses for cable, telex and fax transmissions and for delivery of securities.

- Taxes and duties upon the transfer of securities, including any applicable stamp duties, any stock transfer charges or withholding taxes (i.e., when ordinary shares are deposited or withdrawn from deposit).
- Fees and expenses incurred in connection with the delivery or servicing of ordinary shares on deposit.
- Fees and expenses incurred in connection with complying with exchange control regulations and other regulatory requirements applicable to ordinary shares, ordinary shares deposited securities, ADSs and ADRs.
- Any applicable fees and penalties thereon.

The depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary bank by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary bank and by the brokers (on behalf of their clients) delivering the ADSs to the depositary bank for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary bank to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed or by selling a portion of distributable property to pay the fees. In the case of distributions other than cash (i.e., share dividends, rights), the depositary bank charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary bank sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary bank generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary banks.

In the event of refusal to pay the depositary fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

The depositary has agreed to pay certain amounts to us in exchange for its appointment as depositary. We may use these funds towards our expenses relating to the establishment and maintenance of the ADR program, including investor relations expenses, or otherwise as we see fit. In 2017, we did not collect any reimbursements from the depositary for expenses related to the administration and maintenance of the facility.

#### PART II

## ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

# ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

A. Material Modifications to the Rights of Security Holders

None.

#### B. Use of Proceeds

## U.S. Initial Public Offering

As of December 31, 2017, we have used all of the approximately \$96.0 million of the net proceeds from our U.S. initial public offering as follows:

- approximately \$40.8 million to accelerate and broaden clinical development of the drug candidates for which we retain all worldwide rights, specifically:
  - i approximately \$6.6 million to advance HMPL-523 including the Phase I trial in healthy volunteers in Australia & China and the two Phase I studies in hematological cancer in China and Australia;
  - ii approximately \$20.9 million to advance sulfatinib including the Phase II open-label trial in first-line neuroendocrine tumors in China, the two Phase III trials in pancreatic and extrapancreatic neuroendocrine tumors in China, the Phase I bridging study in the United States, the Phase II trial in thyroid cancer, and the Phase II trial in biliary tract cancer in China;
- iii approximately \$5.0 million to advance epitinib including the Phase II trial in non-small cell lung cancer patients with activating EGFR-mutation positive with brain metastasis in China;
- iv approximately \$1.4 million to advance theliatinib including the Phase I trial in wild-type EGFR-mutation positive non-small cell lung cancer and the Phase Ib trial in esophageal cancer in China;
- v approximately \$3.9 million to advance HMPL-689 including the Phase I dose escalation trial in healthy volunteers in Australia & China; and
- vi approximately \$3.0 million to advance HMPL-453 including initiating the Phase I dose escalation trials in China and Australia.
- approximately \$31.8 million to support our share of the research and development costs of our partnered drug candidates, including:
  - i approximately \$11.5 million to advance savolitinib including preparations to initiate a Phase III study in papillary renal cell carcinoma, the Phase Ib study in second-line, EGFR tyrosine kinase inhibitor refractory non-small cell lung cancer in combination with Iressa, the two Phase Ib trials in c-Met-driven first-line non-small cell lung cancer, and the three Phase Ib trials in gastric cancer with c-Met gene amplification or c-Met over-expression, as monotherapy or in combination with Taxotere;
  - ii approximately \$19.0 million to advance fruquintinib including Phase II and Phase III trials in third-line colorectal cancer, Phase II and Phase III trials in third-line non-small cell lung cancer, a Phase Ib trial in gastric cancer in combination with Taxol, and initiating a Phase II trial in first-line non-small cell lung cancer in combination with Iressa, which we began enrolling in January 2017; and
- iii approximately \$1.3 million to advance new formulations of HMPL-004, including HM004-6599, and other botanical drug candidates.
- approximately \$18.6 million from the net proceeds to support our discovery platform:
  - i approximately \$8.3 million for external research services and supplies; and
  - ii approximately \$10.3 million for our development and discovery research team.
- approximately \$4.8 million to build production facilities to produce both clinical and commercial supply of our drug candidates.

### C-D. Assets Securing Securities; Trustees; Paying Agents

None.

#### ITEM 15. CONTROLS AND PROCEDURES

#### A. Evaluation of Disclosure Controls and Procedures.

As required by Rule 13a-15 under the Exchange Act, management, including our chief executive officer and our chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosure. Based on such evaluation, our management has concluded that, as of December 31, 2017, our disclosure controls and procedures were effective.

## B. 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 defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934. 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 in accordance with U.S. GAAP 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness of our internal control over financial reporting 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.

Our management, with the participation of our chief executive officer and chief financial officer, has assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2017.

## C. Attestation Report of the Independent Registered Public Accounting Firm.

Our independent registered public accounting firm, PricewaterhouseCoopers, has audited the effectiveness of our internal control over financial reporting as of December 31, 2017, as stated in its report, which appears on page F-2 of this annual report.

### D. Changes in Internal Control over Financial Reporting.

There were no changes in our internal controls over financial reporting during fiscal 2017 that have materially and adversely affected, or are reasonably likely to materially and adversely affect, our internal control over financial reporting.

#### ITEM 16. RESERVED

#### ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERTS

Our audit committee consists of Graeme Jack, Paul Carter and Karen Ferrante, with Graeme Jack serving as chairman of the committee. Michael Howell, Christopher Huang and Christopher Nash previously served on our audit committee until March 1, 2017, February 1, 2017 and February 1, 2017, respectively. Graeme Jack, Paul Carter and Karen Ferrante each meet the independence requirements under the rules of the Nasdaq Stock Market and under Rule 10A-3 under the Exchange Act. We have determined that Graeme Jack is an "audit committee financial expert" within the meaning of Item 407 of Regulation S-K. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq Stock Market. For information relating to qualifications and experience of each audit committee member, see Item 6. "Directors, Senior Management and Employees."

### ITEM 16B. CODE OF ETHICS

Our board of directors has adopted a code of ethics applicable to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. This code is intended to qualify as a "code of ethics" within the meaning of the applicable rules of the SEC. Our code of ethics is available on our website at <a href="http://www.chi-med.com/leadership-governance/terms-of-reference-policies/code-of-ethics/">http://www.chi-med.com/leadership-governance/terms-of-reference-policies/code-of-ethics/</a>. Information contained on, or that can be accessed through, our website is not incorporated by reference into this annual report. See Item 6.C. "Board Practices—Code of Ethics" for more information.

## ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

### **Principal Accountant Fees and Services**

The following table summarizes the fees charged by PricewaterhouseCoopers for certain services rendered to our company, including some of our subsidiaries and joint ventures, during 2016 and 2017.

		For the year ended December 31,	
	2017	2016	
	(in thou	ısands)	
Audit fees <sup>(1)</sup>	2,360	2,115	
Tax fees <sup>(2)</sup>		30	
Other service fees <sup>(3)</sup>	105	_	
Total <sup>(4)</sup>	2,465	2,145	

- (1) "Audit fees" means the aggregate fees billed in each of the fiscal years for professional services rendered by PricewaterhouseCoopers for the audit of our annual financial statements and review of our interim financial statements, filing of our Form S-8 and professional services in connection with our initial public offering and follow-on offering in the United States.
- (2) "Tax fees" means the aggregate fees billed in each of the fiscal years for professional services rendered by PricewaterhouseCoopers for tax compliance and tax advice.

- (3) "Other service fees" means the aggregate fees billed in 2017 for professional services rendered by PricewaterhouseCoopers for IT system and security assessment.
- (4) The fees disclosed are exclusive of out-of-pocket expenses and taxes on the amounts paid, which totaled approximately \$82,000 and \$139,000 in 2016 and 2017, respectively.

## **Audit Committee Pre-approval Policies and Procedures**

Our audit committee reviews and pre-approves the scope and the cost of audit services related to us and permissible non-audit services performed by the independent auditors, other than those for *de minimis* services which are approved by the audit committee prior to the completion of the audit. All of the services related to our company provided by PricewaterhouseCoopers listed above have been approved by the audit committee.

#### ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

# ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

### ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

#### ITEM 16G. CORPORATE GOVERNANCE

As permitted by Nasdaq, in lieu of the Nasdaq corporate governance rules, but subject to certain exceptions, we may follow the practices of our home country which for the purpose of such rules is the Cayman Islands. Certain corporate governance practices in the Cayman Islands may differ significantly from corporate governance listing standards as, except for general fiduciary duties and duties of care, Cayman Islands law has no corporate governance regime which prescribes specific corporate governance standards. For example, we follow Cayman Islands corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Global Select Market in respect of the following:

- (i) the majority independent director requirement under Section 5605(b)(1) of the Nasdaq listing rules,
- (ii) the requirement under Section 5605(d) of the Nasdaq listing rules that a remuneration committee comprised solely of independent directors governed by a remuneration committee charter oversee executive compensation, and
- (iii) the requirement under Section 5605(e) of the Nasdaq listing rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee comprised solely of independent directors.

Cayman Islands law does not impose a requirement that our board of directors consist of a majority of independent directors. Nor does Cayman Islands law impose specific requirements on the establishment of a remuneration committee or nominating committee or nominating process.

## ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

### **PART III**

### ITEM 17. FINANCIAL STATEMENTS

See Item 18 "Financial Statements."

#### ITEM 18. FINANCIAL STATEMENTS

Our consolidated financial statements and the consolidated financial statements of our three non-consolidated joint ventures, Shanghai Hutchison Pharmaceuticals, Hutchison Baiyunshan and Nutrition Science Partners, are included at the end of this annual report.

The consolidated financial statements of Nutrition Science Partners relating to the year ended December 31, 2017 included herein are not the Hong Kong statutory annual financial statements of Nutrition Science Partners for that year. As Nutrition Science Partners is a private company, it is not required to deliver its financial statements with its annual returns to the Hong Kong Registrar of Companies and has not done so. Nutrition Science Partners' auditor has separately reported on those financial statements. The auditor's report was unqualified; did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying its report; and did not contain a statement under sections 406(2), 407(2) or (3) of the Hong Kong Companies Ordinance Cap. 622.

#### **EXHIBIT INDEX**

- 1.1\* Memorandum and Articles of Association of Hutchison China MediTech Limited (incorporated by reference to Exhibit 3.1 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 2.1\* Form of Deposit Agreement and all holders and beneficial owners of ADSs issued thereunder (incorporated by reference to Exhibit 4.1 to Amendment No. 4 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on March 4, 2016)
- 2.2\* Form of American Depositary Receipt (incorporated by reference to Exhibit 4.1 to Amendment No. 4 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on March 4, 2016)
- 2.3\* Form of Specimen Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on February 11, 2016)
- 4.1\*\* License and Collaboration Agreement by and between Hutchison MediPharma Limited and AstraZeneca AB (publ) dated as of December 21, 2011 (incorporated by reference to Exhibit 10.9 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.2\*\* Amended and Restated Exclusive License and Collaboration Agreement by and among Hutchison MediPharma Limited, Eli Lilly Trading (Shanghai) Company Limited and Hutchison China MediTech Limited dated as of October 8, 2013 (incorporated by reference to Exhibit 10.10 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.3\*\* Option Agreement by and between Hutchison China MediTech Limited and Eli Lilly and Company dated as of October 8, 2013 (incorporated by reference to Exhibit 10.11 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.4\*\* Joint Venture Agreement by and among Hutchison MediPharma (Hong Kong) Limited, Nestlé Health Science S.A., Nutrition Science Partners Limited and Hutchison China MediTech Limited dated as of November 27, 2012 (incorporated by reference to Exhibit 10.12 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on November 13, 2015)
- 4.5\*\* English translation of Sino-Foreign Joint Venture Contract by and between Guangzhou Baiyunshan Pharmaceutical Holdings Company Limited and Hutchison Chinese Medicine (Guangzhou) Investment Limited dated as of November 28, 2004 (incorporated by reference to Exhibit 10.13 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.6\*\* English translation of Sino-Foreign Joint Venture Contract by and between Shanghai Traditional Chinese Medicine Co., Ltd. and Hutchison Chinese Medicine (Shanghai) Investment Limited dated as of January 6, 2001 (incorporated by reference to Exhibit 10.14 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)

- 4.7\* English translation of First Amendment to Sino-Foreign Joint Venture Contract by and between Shanghai Traditional Chinese Medicine Co., Ltd. and Hutchison Chinese Medicine (Shanghai) Investment Limited dated as of July 12, 2001 (incorporated by reference to Exhibit 10.15 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.8\* English translation of Second Amendment to Sino-Foreign Joint Venture Contract by and between Shanghai Traditional Chinese Medicine Co., Ltd. and Shanghai Hutchison Chinese Medicine (HK) Investment Limited dated as of November 5, 2007 (incorporated by reference to Exhibit 10.16 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.9\* English translation of Third Amendment to Sino-Foreign Joint Venture Contract by and between Shanghai Traditional Chinese Medicine Co., Ltd. and Shanghai Hutchison Chinese Medicine (HK) Investment Limited dated as of June 19, 2012 (incorporated by reference to Exhibit 10.17 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.10\*\* English translation of Fourth Amendment to Sino-Foreign Joint Venture Contract by and between Shanghai Traditional Chinese Medicine Co., Ltd. and Shanghai Hutchison Chinese Medicine (HK) Investment Limited dated as of March 8, 2013 (incorporated by reference to Exhibit 10.18 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.11\* English translation of Sino-Foreign Joint Venture Contract by and between Sinopharm Group Co. Ltd. and Hutchison Chinese Medicine GSP (HK) Holdings Limited dated as of December 18, 2013 (incorporated by reference to Exhibit 10.19 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.12\* Revolving Loan Facility Agreement by and between Hutchison China MediTech (HK) Limited as borrower and The Hongkong and Shanghai Banking Corporation Limited as lender dated January 3, 2013 (incorporated by reference to Exhibit 10.22 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.13\* Form of Executive Employment Agreement for Hutchison China MediTech (HK) Limited executive officers (incorporated by reference to Exhibit 10.23 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.14\* English translation of Form of Executive Employment Agreement for Hutchison MediPharma Limited executive officers (incorporated by reference to Exhibit 10.24 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.15\* Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.25 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 4.16\*\* First Amendment to License and Collaboration Agreement by and between Hutchison MediPharma Limited and AstraZeneca (publ) dated as of August 1, 2016 (incorporated by reference to Exhibit 4.19 to our annual report on Form 20-F filed with the SEC on March 13, 2017)

- 8.1\* List of Significant Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to our Registration Statement on Form F-1 (file no. 333-207447) filed with the SEC on October 16, 2015)
- 12.1\*\* Certification of Chief Executive Officer Required by Rule 13a-14(a)
- 12.2\*\* Certification of Chief Financial Officer Required by Rule 13a-14(a)
- 13.1<sup>†</sup> Certification of Chief Executive Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code
- 13.2<sup>†</sup> Certification of Acting Chief Financial Officer Required by Rule 13a-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code
- 15.1\*\* Consent of PricewaterhouseCoopers, an independent registered accounting firm, regarding the consolidated financial statements of Hutchison China MediTech Limited
- 15.2\*\* Consent of PricewaterhouseCoopers, an independent registered accounting firm, regarding the consolidated financial statements of Nutrition Science Partners Limited
- 15.3\*\* Consent of PricewaterhouseCoopers Zhong Tian LLP, independent accountants, regarding the consolidated financial statements of Shanghai Hutchison Pharmaceuticals Limited
- 15.4\*\* Consent of PricewaterhouseCoopers Zhong Tian LLP, independent accountants, regarding the consolidated financial statements of Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited
- 15.5\*\* Consent of Conyers Dill & Pearman
- 101.INS\*\* XBRL Instance Document
- 101.SCH\*\* XBRL Taxonomy Extension Schema Document
- 101.CAL\*\* XBRL Taxonomy Extension Calculation Linkbase Document
- 101.LAB\*\* XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE\*\* XBRL Taxonomy Extension Presentation Linkbase Document
- 101.DEF\*\* XBRL Taxonomy Extension Definitions Linkbase Document
- \* Previously filed.
- \*\* Filed herewith.
- † Furnished herewith.
- + Confidential treatment previously requested and granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

# **SIGNATURES**

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

# **Hutchison China MediTech Limited**

By: /s/ Christian Hogg

Name: Christian Hogg

Title: Chief Executive Officer

Date: March 12, 2018

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### Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Hutchison China MediTech Limited

## Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Hutchison China MediTech Limited and its subsidiaries as of December 31, 2017 and 2016, and the related consolidated statements of operations, of comprehensive (loss)/income, of changes in shareholders' equity and of cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the COSO.

# Change in Accounting Principle

As discussed in Note 23 (ii) to the consolidated financial statements, the Company changed the manner in which it classifies deferred income tax assets and liabilities in 2017.

### Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 15 of Form 20-F. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting 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 audits also included performing

such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

## Definition and Limitations of Internal Control over Financial Reporting

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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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.

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.

/s/ PricewaterhouseCoopers Hong Kong March 12, 2018

We have served as the Company's auditor since 2005, which includes periods before the Company became subject to SEC reporting requirements.

# Hutchison China MediTech Limited Consolidated Balance Sheets (in US\$'000)

		Decemb	er 31,
	Note	2017	2016
Assets			
Current assets			
Cash and cash equivalents	5	85,265	79,431
Short-term investments	6	273,031	24,270
Accounts receivable—third parties	7	38,410	40,812
Accounts receivable—related parties	22(ii)	3,860	4,223
Other receivables, prepayments and deposits	8	11,296	4,314
Amounts due from related parties	22(ii)	8,544	1,136
Inventories	9	11,789	12,822
Deferred tax assets	23(ii)		372
Total current assets		432,195	167,380
Property, plant and equipment	10	14,220	9,954
Leasehold land		1,261	1,220
Goodwill		3,308	3,137
Other intangible asset		430	469
Deferred tax assets	23(ii)	633	_
Long-term prepayment	` '	1,648	1,771
Investments in equity investees	11	144,237	158,506
Total assets		597,932	342,437
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable	12	24,365	35,538
Other payables, accruals and advance receipts	13	40,953	31,716
Income tax payable	23(iii)	979	274
Deferred revenue		1,295	962
Amounts due to related parties	22(ii)	7,021	5,308
Short-term bank borrowings	14	29,987	19,957
Deferred tax liabilities	23(ii)	· —	1,364
Total current liabilities		104,600	95,119
Deferred tax liabilities	23(ii)	4,452	3,997
Long-term bank borrowings	14	´—	26,830
Deferred revenue		809	2,039
Other deferred income		1,988	2,263
Other non-current liabilities		1,117	8,129
Total liabilities		112,966	138,377
Commitments and contingencies	15	112,700	150,577
Communication and Contingencies	10		
Company's shareholders' equity			
Ordinary shares; \$1.00 par value; 75,000,000 shares authorized; 66,447,037 and			
60,705,823 shares issued at December 31, 2017 and 2016 respectively	17	66,447	60,706
Additional paid-in capital		496,960	208,196
Accumulated losses		(107,104)	(80,357)
Accumulated other comprehensive income/(loss)		5,430	(4,275)
Total Company's shareholders' equity		461,733	184,270
Non-controlling interests		23,233	19,790
Total shareholders' equity		484,966	204,060
Total liabilities and shareholders' equity		597,932	342,437

The accompanying notes are an integral part of these consolidated financial statements.

# Hutchison China MediTech Limited Consolidated Statements of Operations (in US\$'000, except share and per share data)

		Year Ended December 31,		
	Note	2017	2016	2015
Revenues				
Sales—third parties		196,720	171,058	118,113
Sales—related parties	22(i)	8,486	9,794	8,074
Revenue from license and collaboration agreements—third				
parties	19	26,315	26,444	44,060
Revenue from research and development services—third parties		_	355	2,573
Revenue from research and development services—related				
parties	22(i)	9,682	8,429	5,383
Total revenues	25	241,203	216,080	178,203
Operating expenses				
Costs of sales—third parties		(169,764)	(149,132)	(104,859)
Costs of sales—related parties		(6,056)	(7,196)	(5,918)
Research and development expenses	20	(75,523)	(66,871)	(47,368)
Selling expenses		(19,322)	(17,998)	(10,209)
Administrative expenses		(23,955)	(21,580)	(19,620)
Total operating expenses		(294,620)	(262,777)	(187,974)
Loss from operations		(53,417)	(46,697)	(9,771)
Other income/(expense)		(, -,	(	(- ) )
Interest income	25	1,220	502	451
Other income		808	609	386
Interest expense	25	(1,455)	(1,631)	(1,404)
Other expense		(692)	(139)	(202)
Total other income/(expense)		(119)	(659)	(769)
Loss before income taxes and equity in earnings of equity				
investees		(53,536)	(47,356)	(10,540)
Income tax expense	23(i)	(3,080)	(4,331)	(1,605)
Equity in earnings of equity investees, net of tax	11	33,653	66,244	22,572
Net (loss)/income		(22,963)	14,557	10,427
Less: Net income attributable to non-controlling interests		(3,774)	(2,859)	(2,434)
Net (loss)/income attributable to the Company		(26,737)	11,698	7,993
Accretion on redeemable non-controlling interests				(43,001)
Net (loss)/income attributable to ordinary shareholders of				
the Company		(26,737)	11,698	(35,008)
(Losses)/earnings per share attributable to ordinary shareholders of the Company—basic (US\$ per share)	24(i)	(0.43)	0.20	(0.64)
(Losses)/earnings per share attributable to ordinary	(-)	(3.10)	2.20	(3.0.)
shareholders of the Company—diluted (US\$ per share)	24(ii)	(0.43)	0.20	(0.64)
Number of shares used in per share calculation—basic	24(i)	61,717,171	59,715,173	54,659,315
Number of shares used in per share calculation—diluted	24(ii)	61,717,171	59,971,050	54,659,315

The accompanying notes are an integral part of these consolidated financial statements.

# Hutchison China MediTech Limited Consolidated Statements of Comprehensive (Loss)/Income (in US\$'000)

	Year Ended December 31,		
	2017	2016	2015
Net (loss)/income	(22,963)	14,557	10,427
Other comprehensive income/(loss)			
Foreign currency translation gain/(loss)	10,964	(10,722)	(5,557)
Total comprehensive (loss)/income	(11,999)	3,835	4,870
Less: Comprehensive income attributable to non-controlling interests	(5,033)	(1,427)	(1,732)
Total comprehensive (loss)/income attributable to the Company	(17,032)	2,408	3,138

The accompanying notes are an integral part of these consolidated financial statements.

## Hutchison China MediTech Limited Consolidated Statements of Changes in Shareholders' Equity (in US\$'000, except share data in '000)

	Ordinary Shares Number	Ordinary Shares Value	Additional Paid-in Capital	Accumulated Losses	Accumulated Other Comprehensive Income/(Loss)	Total Company's Shareholders' Equity	Non- controlling Interests	Total Equity
As at December 31, 2014	53,076	53,076	76,256	(100,051)	9,870	39,151	17,764	56,915
Net income	´ —	´ —	´ —	7,993	´ —	7,993	2,434	10,427
Accretion to redemption value of						/		
redeemable non-controlling interests	_	_	(43,001)	_	_	(43,001)	_	(43,001)
Issuance in exchange for redeemable non-controlling interest	3,214	3,214	80,823			84,037		84,037
Issuances in relation to share option	3,214	3,214	00,023			04,037		04,037
exercises	243	243	1,131	_	_	1,374	_	1,374
Share-based compensation			, -			<b>,</b>		,
Share options	_	_	168	_	_	168	_	168
Long-term incentive plan ("LTIP")	_	_	233	_	_	233	_	233
			401		_	401		401
LTIP—treasury shares acquired and held								
by Trustee	_	_	(1,786)	_	_	(1,786)	_	(1,786)
Dividend paid to a non-controlling shareholder of a subsidiary	_	_	(2,700)	_	_	(1,700)	(590)	(590)
Dilution of interests in a subsidiary in							(370)	(370)
relation to exercise of share options of								
a subsidiary	_	_	_	42	_	42	15	57
Transfer between reserves	_	_	24	(24)	_	_	<del>-</del>	_
Foreign currency translation adjustments					(4,855)	(4,855)	(702)	(5,557)
As at December 31, 2015	56,533	56,533	113,848	(92,040)	5,015	83,356	18,921	102,277
Net income				11,698		11,698	2,859	14,557
Issuance in relation to public offering	4,080	4.080	106,080	11,090		110,160	2,639	110,160
Issuance costs			(14,227)	_	_	(14,227)	_	(14,227)
Issuances in relation to share option exercises	93	93	333	_	_	426	_	426
Share-based compensation								
Share options	_	_	1,373	_	_	1,373	4	1,377
LTIP			1,378			1,378	2	1,380
	_	_	2,751	_	_	2,751	6	2,757
LTIP—treasury shares acquired and held by Trustee		_	(604)		_	(604)		(604)
Dividend paid to a non-controlling			(001)			(001)		(001)
shareholder of a subsidiary	_	_	_	_	_	_	(564)	(564)
Transfer between reserves	_	_	15	(15)	_	_	`—	`—
Foreign currency translation adjustments					(9,290)	(9,290)	(1,432)	(10,722)
As at December 31, 2016	60,706	60,706	208,196	(80,357)	(4,275)	184,270	19,790	204,060
Net loss	_	_		(26,737)	_	(26,737)	3,774	(22,963)
Issuance in relation to public offering	5,685	5,685	295,615	`	_	301,300		301,300
Issuance costs	_	_	(8,610)	_	_	(8,610)	_	(8,610)
Issuances in relation to share option exercises	56	56	324	_	_	380	_	380
Share-based compensation								
Share options		_	1,255	_	_	1,255	3	1,258
LTIP			1,537			1,537	1	1,538
	_	_	2,792	_	_	2,792	4	2,796
LTIP—treasury shares acquired and held by Trustee	_	_	(1,367)	_	_	(1,367)	_	(1,367)
Dividends paid to non-controlling shareholders of subsidiaries	_	_		_	_	_	(1,594)	(1,594)
Transfer between reserves	_	_	10	(10)	_	_	` —	` —
Foreign currency translation adjustments					9,705	9,705	1,259	10,964
As at December 31, 2017	66,447	66,447	496,960	(107,104)	5,430	461,733	23,233	484,966

The accompanying notes are an integral part of these consolidated financial statements.

# Hutchison China MediTech Limited Consolidated Statements of Cash Flows (in US\$'000)

		Year Ended December 31,			
	Note	2017	2016	2015	
Net cash used in operating activities	26	(8,943)	(9,569)	(9,385)	
Investing activities					
Purchases of property, plant and equipment	10	(5,019)	(4,327)	(3,324)	
Deposits in short-term investments		(325,032)	(80,857)	_	
Proceeds from short-term investments		76,271	56,587	12,179	
Investment in an equity investee	11	(7,000)	(5,000)		
Net cash (used in)/generated from investing activities		(260,780)	(33,597)	8,855	
Financing activities					
Proceeds from issuance of ordinary shares		301,680	110,586	1,374	
Proceeds from exercise of share options of a subsidiary		_	_	57	
Purchases of treasury shares		(1,367)	(604)	(1,786)	
Dividends paid to non-controlling shareholders of					
subsidiaries		(1,594)	(564)	(590)	
Repayment of loan to a non-controlling shareholder of			(4.000)		
a subsidiary		22.540	(1,000)	2 205	
Proceeds from bank borrowings		32,540	25,128	3,205	
Repayment of bank borrowings		(49,487)	(28,205)	(6,410)	
Payment of issuance costs		(8,576)	(12,906)	(1,321)	
Net cash generated from/(used in) financing activities		273,196	92,435	(5,471)	
Net increase/(decrease) in cash and cash equivalents		3,473	49,269	(6,001)	
Effect of exchange rate changes on cash and cash					
equivalents		2,361	(1,779)	(1,004)	
		5,834	47,490	(7,005)	
Cash and cash equivalents					
Cash and cash equivalents at beginning of year		79,431	31,941	38,946	
Cash and cash equivalents at end of year		85,265	79,431	31,941	
Supplemental disclosure for cash flow information					
Cash paid for interest		763	1,570	1,220	
Cash paid for tax, net of refunds		3,836	2,664	510	
Supplemental disclosure for non-cash activities					
Accruals made for purchases of property, plant and					
equipment		1,054		_	
Accrued issuance costs for public offering		34	_	3,125	
Vesting of treasury shares for LTIP	18 (iii)	1,800	_	_	
Capitalization of amounts due from related parties to					
investments in equity investees		_	7,000	_	
Issuance of ordinary shares in exchange of redeemable	4.5			04.00=	
non-controlling interests	16	_		84,037	

The accompanying notes are an integral part of these consolidated financial statements.

## Hutchison China MediTech Limited Notes to the Consolidated Financial Statements

## 1. Organization and Nature of Business

Hutchison China MediTech Limited (the "Company") and its subsidiaries (together the "Group") are principally engaged in researching, developing, manufacturing and selling pharmaceuticals and healthcare products. The Group and its equity investees have research and development facilities and manufacturing plants in the People's Republic of China (the "PRC") and sell their products mainly in the PRC and Hong Kong.

The Company considers Hutchison Healthcare Holdings Limited as its immediate holding company and CK Hutchison Holdings Limited ("CK Hutchison") as its ultimate holding company.

The Company was incorporated in the Cayman Islands on December 18, 2000 as an exempted company with limited liability under the Companies Law (2000 Revision), Chapter 22 of the Cayman Islands. The address of its registered office is P.O. Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

The Company's ordinary shares are listed on the AIM market of the London Stock Exchange, and its American depositary shares ("ADS"), each representing one-half of one ordinary share, are traded on the Nasdaq Global Select Market.

## Liquidity

As at December 31, 2017, the Group had accumulated losses of US\$107,104,000, primarily due to its significant spending in research and development activities. The Group regularly monitors current and expected liquidity requirements to ensure that it maintains sufficient cash balances and adequate credit facilities to meet its liquidity requirements in the short and long term. As at December 31, 2017, the Group had cash and cash equivalents of US\$85,265,000, short-term investments of US\$273,031,000 and unutilized bank borrowing facilities of US\$121,282,000. Short-term investments comprised of bank deposits maturing over three months. As at December 31, 2016, the Group had cash and cash equivalents of US\$79,431,000, short-term investments of US\$24,270,000 and unutilized bank borrowing facilities of US\$70,000,000. The Group's operating plan includes the continued receipt of dividends from certain of its equity investees. The increase in cash balances is primarily due to a public follow-on offering of the Company's ADS in October 2017, which raised net proceeds of US\$292,690,000. Additionally, dividends received from equity investees for the years ended December 31, 2017, 2016 and 2015 were US\$55,586,000, US\$30,528,000 and US\$6,410,000 respectively.

Based on the Group's operating plan, the existing cash and cash equivalents, short-term investments and unutilized bank borrowing facilities are considered to be sufficient to meet the cash requirements to fund planned operations and other commitments for at least the next twelve months (the look-forward period used).

## 2. Particulars of Principal Subsidiaries and Equity Investees

		attribu	interest table to Group	
	Place of establishment		at aber 31,	
Name	and operations	2017	2016	Principal activities
Subsidiaries				
Hutchison MediPharma Limited ("HMPL")	PRC	99.75%	99.75%	Research and development of pharmaceutical products
Hutchison Whampoa Sinopharm Pharmaceuticals (Shanghai) Company Limited ("Hutchison Sinopharm")	PRC	51%	51%	Provision of sales, distribution and marketing services to pharmaceutical manufacturers
Hutchison Hain Organic (Hong Kong) Limited ("HHOL") (note (a))	Hong Kong	50%	50%	Wholesale and trading of healthcare and consumer products
Hutchison Hain Organic (Guangzhou) Limited ("HHOGZL") (note (a))	PRC	50%	50%	Wholesale and trading of healthcare and consumer products
Hutchison Healthcare Limited ("HHL")	PRC	100%	100%	Manufacture and distribution of healthcare products
Hutchison Consumer Products Limited	Hong Kong	100%	100%	Wholesale and trading of healthcare and consumer products
Equity investees Shanghai Hutchison				
Pharmaceuticals Limited ("SHPL")	PRC	50%	50%	Manufacture and distribution of prescription drug products
Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited ("HBYS") (note (b))	PRC	40%	40%	Manufacture and distribution of over-the-counter drug products
Nutrition Science Partners Limited ("NSPL") (note (c))	Hong Kong	49.88%	49.88%	Research and development of pharmaceutical products

#### Notes:

- (a) HHOL and HHOGZL are regarded as subsidiaries of the Company, as while both shareholders of these subsidiaries have equal representation at their respective boards, in the event of a deadlock, the Group has a casting vote and is therefore able to unilaterally control the financial and operating policies of HHOL and HHOGZL.
- (b) The 50% equity interest in HBYS is held by an 80% owned subsidiary of the Group. The effective equity interest of the Group in HBYS is therefore 40% for the years presented.
- (c) The 50% equity interest in NSPL is held by a 99.75% owned subsidiary of the Group. The effective equity interest of the Group in NSPL is therefore 49.88% for the years presented.

## 3. Summary of Significant Accounting Policies

#### Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements reflect the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Investments in equity investees over which the Group has significant influence are accounted for using the equity method. All inter-company balances and transactions have been eliminated in consolidation. The consolidated financial statements have been

prepared in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP").

## Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities and other intangible assets as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as useful lives of property, plant and equipment, write-down of inventories, allowance for doubtful accounts, share-based compensation, impairments of long-lived assets, impairment of other intangible asset and goodwill, taxes on income, tax valuation allowances, revenues and cost accruals from research and development projects. Actual results could differ from those estimates.

## Foreign Currency Translation

The Group's functional currency is Renminbi ("RMB") but the presentation currency is U.S. dollar ("US\$"). The financial statements of the Company's subsidiaries with a functional currency other than the US\$ have been translated into the Company's reporting currency, the US\$. All assets and liabilities of the subsidiaries are translated using year-end exchange rates and revenues and expenses are translated at average exchange rates for the year. Translation adjustments are reflected in accumulated other comprehensive income/(loss) in shareholders' equity.

Net foreign currency exchange losses of US\$316,000, US\$109,000 and US\$79,000 were recorded in other expense in the consolidated statements of operations for the years ended December 31, 2017, 2016 and 2015 respectively.

## Cash and Cash Equivalents

The Group considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash on hand and bank deposits and are stated at cost, which approximates fair value.

#### Short-term Investments

Short-term investments include deposits placed with banks with original maturities of more than three months but less than one year.

#### Concentration of Credit Risk

Financial instruments that potentially expose the Group to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments, accounts receivable, other receivables and amounts due from related parties.

The Group places substantially all of its cash and cash equivalents and short-term investments in major financial institutions, which management believes are of high credit quality. The Group has a practice to limit the amount of credit exposure to any particular financial institution.

The Group has no significant concentration of credit risk. The Group has policies in place to ensure that sales are made to customers with an appropriate credit history and the Group performs periodic credit evaluations of its customers. Normally the Group does not require collateral from trade debtors.

#### Foreign Currency Risk

The Group's operating transactions and its assets and liabilities are mainly denominated in RMB, which is not freely convertible into foreign currencies. In the PRC, the Group's cash and cash equivalents denominated in RMB are subject to such government controls. The value of the RMB is subject to fluctuations from central government policy changes and international economic and political developments that affect the supply and demand of RMB in the foreign exchange market. In the PRC, certain foreign exchange transactions are required by law to be transacted only by authorized financial institutions at exchange rates set by the People's Bank of China (the "PBOC"). Remittances in currencies other than RMB by the Group in the PRC must be processed through the PBOC or other PRC foreign exchange regulatory bodies which require certain supporting documentation in order to complete the remittance.

#### Fair Value of Financial Instruments

The fair value of financial instruments that are measured at fair value is determined according to a fair value hierarchy that prioritizes the inputs and assumptions used, and the valuation techniques used. The three levels of the fair value hierarchy are described as follows:

Level 1	Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.
Level 2	Inputs are quoted prices for similar assets or liabilities in active markets; or quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
Level 3	Inputs are unobservable inputs based on the Group's assumptions and valuation techniques used to measure assets or liabilities at fair value. The inputs require significant management judgment or estimation.

The assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of assets and liabilities and their placement within the fair value hierarchy levels.

The fair value of assets and liabilities is established using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, and a fair value hierarchy is established based on the inputs used to measure fair value.

## Accounts Receivable

Accounts receivable are stated at the amount management expects to collect from customers based on their outstanding invoices. Management reviews accounts receivable regularly to determine if any receivable will potentially be uncollectible. Estimates are used to determine the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value. The amount of the allowance for doubtful accounts is recognized in the consolidated statements of operations.

### **Inventories**

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the weighted average cost method. The cost of finished goods comprises raw materials, direct labor, other direct costs and related production overheads (based on normal operating capacity). Net realizable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses. A provision for excess and obsolete inventory will be made based primarily on forecasts of product demand

and production requirements. The excess balance determined by this analysis becomes the basis for excess inventory charge and the written-down value of the inventory becomes its cost. Written-down inventory is not written up if market conditions improve.

## Property, Plant and Equipment

Property, plant and equipment consist of buildings, leasehold improvements, plant and equipment, furniture and fixtures, other equipment and motor vehicles. Property, plant and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the depreciable assets.

Buildings	20 years
Plant and equipment	5-10 years
Furniture and fixtures, other	
equipment and motor	
vehicles	4-5 years
Leasehold improvements	Shorter of (a) 5 years or (b) remaining term of lease

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in the consolidated statements of operations in the year of disposition. Additions and improvements that extend the useful life of an asset are capitalized. Repairs and maintenance costs are expensed as incurred.

## Impairment of Long-Lived Assets

The Group evaluates the recoverability of long-lived assets in accordance with authoritative guidance on accounting for the impairment or disposal of long-lived assets. The Group evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of these assets may not be recoverable. If such indicators exist, the first step of the impairment test is performed to assess if the carrying value of the net assets exceeds the undiscounted cash flows of the assets. If yes, the second step of the impairment test is performed in order to determine if the carrying value of the net assets exceeds the fair value. If yes, impairment is recognized for the excess.

#### Leasehold Land

Leasehold land represents fees paid to acquire the right to use the land on which various plants and buildings are situated for a specified period of time from the date the respective right was granted and are stated at cost less accumulated amortization and impairment loss, if any. Amortization is computed using the straight-line basis over the lease period of 50 years.

## Goodwill

Goodwill represents the excess of the purchase price plus fair value of non-controlling interests over the fair value of identifiable assets and liabilities acquired. Goodwill is not amortized, but is tested for impairment at the reporting unit level on at least an annual basis or when an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying amount. When performing an evaluation of goodwill impairment, the Group has the option to first assess qualitative factors, such as significant events and changes to expectations and activities that may have occurred since the last impairment evaluation, to determine if it is more likely than not that goodwill might be impaired. If as a result of the qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, the quantitative fair value test is performed to determine if the fair value of the reporting unit exceeds its carrying value. No impairment of goodwill occurred in the years presented.

The Group has adopted Accounting Standards Update ("ASU") 2017-04, Simplifying the Test for Goodwill Impairment, for annual goodwill impairment tests performed on testing dates after January 1, 2017. This guidance removes Step 2 of the goodwill impairment test, which required the estimation of an implied fair value of goodwill in the same manner as the calculation of goodwill upon a business combination. For prior years' annual goodwill impairment tests, the Group determined that the fair values of their reporting units exceeded their carrying values and Step 2 has never been required.

## Other Intangible Assets

Other intangible assets with finite useful lives are carried at cost less accumulated amortization and impairment loss, if any. Amortization is computed using the straight-line basis over the estimated useful lives of the assets.

## **Borrowings**

Borrowings are recognized initially at fair value, net of debt issuance costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of debt issuance costs) and the redemption value is recognized in the consolidated statements of operations over the period of the borrowings using the effective interest method.

## **Ordinary Shares**

The Company's ordinary shares are stated at par value of US\$1.00 per ordinary share. The difference between the consideration received, net of issuance cost, and the par value is recorded in additional paid-in capital.

## Treasury Shares

The Group accounts for treasury shares under the cost method. The treasury shares were purchased for the purpose of the LTIP.

## Convertible Preferred Shares

When the Company or its subsidiaries issue preferred shares, the Group assesses whether such instruments should be liabilities, mezzanine equity, or permanent equity classified based on multiple indicators such as redemption features, conversion features, voting rights and other embedded features. Freestanding equity instruments with mandatory redemption requirements, embodying an obligation to repurchase the issuer's equity shares by transferring assets, or certain obligations to issue a variable number of shares, are treated as liability-classified instruments. Equity instruments that are redeemable at the option of the holder or not solely within the Group's control are classified as mezzanine equity of the issuer entity (and redeemable non-controlling interests in the consolidated financial statements of the Group if preferred shares are issued by its subsidiaries). Subsequent measurements of financing instruments are driven by the instruments' balance sheet classification.

The Group also reviews the terms of each convertible instrument and determines whether the host instrument is more akin to debt or equity based on the economic characteristics and risks in order to evaluate if there were any embedded features which would require bifurcation and separate accounting from the host contract. For embedded conversion features that are not required to be separated, the Group analyzes the accounting conversion price and the Company's share price at the commitment date to identify any beneficial conversion features.

For any amendment to the terms of the preferred shares not classified as liabilities, the Group assesses whether the amendment is an extinguishment or a modification using the fair value model. The Group considers a significant change in fair value immediately after the amendment to be substantive and to

trigger extinguishment. A change in fair value which is not significant immediately after the amendment is considered non-substantive and thus is subject to modification accounting. When preferred shares are extinguished, the difference between the fair value of the consideration transferred to the preferred shareholders and the carrying amount of such preferred shares (net of issuance costs) is treated as a deemed dividend to the preferred shareholders. When preferred shares are modified and such modification results in a value transfer between preferred shareholders and ordinary shareholders, the change in fair value resulting from the amendment is treated as a deemed dividend to or from the preferred shareholders.

## Share-Based Compensation

## Share options

The Group recognizes share-based compensation expense on share options granted to employees and directors based on their estimated grant date fair value using the Polynomial model. This Polynomial pricing model uses various inputs to measure fair value, including estimated market value of the Company's underlying ordinary shares at the grant date, contractual terms, estimated volatility, risk-free interest rates and expected dividend yields. The Group recognizes share-based compensation expense in the consolidated statements of operations on a graded vesting basis over the requisite service period.

The Group has adopted ASU 2016-09, Improvements to Employee Share-Based Payment Accounting on January 1, 2017. This guidance permitted the Group to make an accounting policy election to account for forfeitures as they occur. The Group has elected to account for forfeitures as they occur and adopted this election using the modified retrospective approach as required with no cumulative effect adjustment. Prior to January 1, 2017, the Group applied an estimated forfeiture rate derived from historical and expected future employee termination behavior.

Share options are classified as equity-settled awards. Share-based compensation expense, when recognized, is charged to the consolidated statements of operations with the corresponding entry to additional paid-in capital.

#### LTIP

The Group recognizes the share-based compensation expense on the LTIP awards based on a fixed or determinable monetary amount on a straight line basis for each annual tranche awarded over the requisite period. For LTIP awards with performance targets, prior to their determination date, the amount of LTIP awards that is expected to vest takes into consideration the achievement of the performance conditions and the extent to which the performance conditions are likely to be met. Performance conditions vary by awards, including targets for shareholder returns, free cash flows, revenues, net profit after taxes and/or the achievement of clinical and regulatory milestones.

These LTIP awards are classified as liability-settled awards before the determination date (i.e. the date when the achievement of any performance conditions are known), as they settle in a variable number of shares based on a determinable monetary amount, which is determined upon the actual achievement of performance targets. As the extent of achievement of the performance targets is uncertain prior to the determination date, a probability based on management's assessment of the achievement of the performance targets has been assigned to calculate the amount to be recognized as an expense over the requisite period.

After the determination date or if the LTIP awards have no performance conditions, the LTIP awards are classified as equity-settled awards. If the performance target is achieved, the Group will pay the determined monetary amount to a trustee appointed by the Group (the "Trustee") to purchase ordinary shares of the Company or the equivalent ADS. Any cumulative compensation expense previously recognized as a liability will be transferred to additional paid in capital, as an equity-settled award. If the performance target is not achieved, no ordinary shares or ADS of the Company will be purchased and the amount previously recorded in the liability will be reversed and included in the consolidated statements of operations.

#### **Defined Contribution Plans**

The Group's subsidiaries in the PRC participate in a government-mandated multi-employer defined contribution plan pursuant to which certain retirement, medical and other welfare benefits are provided to employees. The relevant labor regulations require the Group's subsidiaries in the PRC to pay the local labor and social welfare authority's monthly contributions at a stated contribution rate based on the monthly basic compensation of qualified employees. The relevant local labor and social welfare authorities are responsible for meeting all retirement benefits obligations and the Group's subsidiaries in the PRC have no further commitments beyond their monthly contributions. The contributions to the plan are expensed as incurred.

The Group also makes payments to other defined contribution plans for the benefit of employees employed by subsidiaries outside the PRC. The defined contribution plans are generally funded by the relevant companies and by payments from employees.

The Group's contributions to defined contribution plans for the years ended December 31, 2017, 2016 and 2015 amounted to US\$2,092,000, US\$2,286,000 and US\$1,653,000 respectively.

#### Revenue Recognition—Accounting Standard Codification 605

#### Sales

Revenue from sales of goods in the Commercial Platform segment are recognized when goods are delivered and title passes to the customer and there are no further obligations to the customer. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations. Sales discounts are issued to customers as direct discounts at the point-of-sale or indirectly in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns.

Revenue from sales of services in the Commercial Platform segment are recognized based on amounts that can be invoiced to the customer. The amount that can be invoiced corresponds directly with the value to the customer for performance completed to date.

## Revenues from research and development projects

The Group recognizes revenue for the performance of services when each of the following four criteria are met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

The Group follows Accounting Standard Codification ("ASC") 605-25, Revenue Recognition—Multiple-Element Arrangements and ASC 808, Collaborative Arrangements, if applicable, to determine the recognition of revenue under the Group's license and collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to the Group's intellectual property, (ii) materials and technology, (iii) clinical supply, and/or (iv) participation in joint research or joint steering committees. The payments the Group may receive under these arrangements typically include one or more of the following: non-refundable, upfront license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The Group determines the estimated selling price for deliverables within each agreement using vendor-specific objective evidence ("VSOE") of selling price, if available, or third-party evidence of selling price if VSOE is not available, or the Group's best estimate of selling price, if neither VSOE nor third-party evidence is available. Determining the best estimate of selling price for a deliverable requires significant judgment. The Group typically uses its best estimate of a selling price to estimate the selling price for licenses to development work, since it often does not have VSOE or third-party evidence of selling price for these deliverables. In those circumstances where the Group applies its best estimate of selling price to determine the estimated selling price of a license to development work, it considers market conditions as well as entity-specific factors, including those factors contemplated in negotiating the agreements as well as internally developed estimates that include assumptions related to the market opportunity, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating its best estimate of selling price, the Group evaluates whether changes in the key assumptions used to determine its best estimate of selling price will have a significant effect on the allocation of arrangement consideration between deliverables. The Group recognizes consideration allocated to an individual element when all other revenue recognition criteria are met for that element.

The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

The Group typically receives non-refundable, upfront payments when licensing the Group's intellectual property, which often occurs in conjunction with a research and development agreement. If management believes that the license to the Group's intellectual property has stand-alone value, the Group generally recognizes revenue attributed to the license upon delivery provided that there are no future performance requirements for use of the license. When management believes that the license to the Group's intellectual property does not have stand-alone value, the Group will recognize revenue attributed to the license ratably over the contractual or estimated performance period. For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, the Group recognizes a portion of the payment as revenue when the specific milestone is achieved, and the contingency is removed. Other contingent event-based payments for which payment is either contingent solely upon the passage of time or the result of a collaborator's performance are recognized when earned. The Group's collaboration and license agreements generally include contingent milestone payments related to specified pre-clinical research and development milestones, clinical development milestones, regulatory milestones and sales-based milestones. Pre-clinical research and development milestones are typically payable upon the selection of a compound candidate for the next stage of research and development. Clinical development milestones are typically payable when a product candidate initiates or advances in clinical trial phases or achieves defined clinical events such as proof-of-concept. Regulatory milestones are typically payable upon submission for marketing approval with regulatory authorities or upon receipt of actual marketing approvals for a compound, approvals for additional indications, or upon the first commercial sale. Sales-based milestones are typically payable when annual sales reach specified levels.

At the inception of each arrangement that includes milestone payments, the Group evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (i) the entity's performance to achieve the milestone or (ii) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Group evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

## Research and Development Expenses

Research and development expenses consist primarily of salaries and benefits, share-based compensation, materials and supplies, contracted research, consulting arrangements and other expenses incurred to sustain the Group's research and development programs. Research and development costs are expensed as incurred.

#### **Government Incentives**

Incentives from governments are recognized at their fair values. Government incentives that are received in advance are deferred and recognized in the consolidated statements of operations over the period necessary to match them with the costs that they are intended to compensate. Government incentives in relation to the achievement of stages of research and development projects are recognized in the consolidated statements of operations when amounts have been received and all attached conditions have been met. Non-refundable incentives received without any further obligations or conditions attached are recognized immediately in the consolidated statements of operations.

## **Operating Leases**

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the consolidated statements of operations on a straight-line basis over the period of the leases.

Total operating lease rentals for buildings for the years ended December 31, 2017, 2016 and 2015 amounted to US\$2,285,000, US\$1,838,000 and US\$1,426,000 respectively. Sub-lease rentals for the years ended December 31, 2017, 2016 and 2015 amounted to US\$274,000, US\$228,000 and US\$229,000 respectively.

#### Interest Income

Interest generated from cash and cash equivalents and short-term investments is recorded over the period earned. It is measured based on the actual amount of interest the Group earns.

## Income Taxes

The Group accounts for income taxes under the liability method. Under the liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the income tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some of the net deferred income tax asset will not be realized.

The Group accounts for an uncertain tax position in the consolidated financial statements only if it is more likely than not that the position is sustainable based on its technical merits and consideration of the relevant tax authority's widely understood administrative practices and precedents. If the recognition threshold is met, the Group records the largest amount of tax benefit that is greater than 50 percent likely to be realized upon ultimate settlement.

#### Comprehensive (Loss)/Income

Comprehensive (loss)/income is defined as the change in equity of a business enterprise during a period from transactions, and other events and circumstances from non-owner sources, and currently consists of net (loss)/income and foreign currency translation gain/(loss) related to the Company's subsidiaries.

## (Losses)/Earnings per Share

Basic (losses)/earnings per share is computed by dividing net (loss)/income attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year. Weighted average number of ordinary shares outstanding during the period excludes treasury shares. In addition, periodic accretion on preferred shares of Hutchison MediPharma Holdings Limited ("HMHL") (Note 16) is recorded as a deduction to consolidated net (loss)/income to arrive at net (loss)/income attributable to ordinary shareholders of the Company for purposes of calculating the consolidated basic (losses)/earnings per share.

Diluted (losses)/earnings per share is computed by dividing net (loss)/income attributable to ordinary shareholders by the weighted average number of ordinary shares and dilutive ordinary share equivalents outstanding during the period. Dilutive ordinary share equivalents include ordinary shares and treasury shares issuable upon the exercise or settlement of share-based awards issued by the Company using the treasury stock method. In determining the impact from share-based awards and convertible preferred shares issued by HMHL, the Company first calculates the diluted earnings per share at HMHL and includes in the numerator of consolidated (losses)/earnings per share the amount based on the diluted earnings per share of HMHL multiplied by the number of shares owned by the Company. The computation of diluted (losses)/earnings per share does not assume conversion, exercise, or contingent issuance of securities that would have an anti-dilutive effect.

## Segment Reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief executive officer who is the Group's chief operating decision maker. The chief operating decision maker reviews the Group's internal reporting in order to assess performance and allocate resources and determined that the Group's reportable segments are as disclosed in Note 25.

## **Discontinued Operations**

A discontinued operation is a component of the Group's business, the operations and cash flows of which can be clearly distinguished from the rest of the Group and which represents a separate major line of business or geographic area of operations, or is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations, or is a subsidiary acquired exclusively with a view to resale. When an operation is classified as discontinued, a single amount is presented in the statements of operations, which comprises the post tax profit or loss of the discontinued operation.

## Profit Appropriation and Statutory Reserves

The Group's subsidiaries and equity investees established in the PRC are required to make appropriations to certain non-distributable reserve funds.

In accordance with the laws applicable to the Foreign Investment Enterprises established in the PRC, the Group's subsidiaries and equity investees registered as wholly-owned foreign enterprise have to make appropriations from its after-tax profit (as determined under generally accepted accounting principles in the PRC ("PRC GAAP") to reserve funds including general reserve fund, the enterprise expansion fund and staff bonus and welfare fund. The appropriation to the general reserve fund must be at least 10% of the after-tax profits calculated in accordance with PRC GAAP. Appropriation is not required if the general reserve fund has reached 50% of the registered capital of the company. Appropriation to the enterprise expansion fund and staff bonus and welfare fund is made at the company's discretion.

The use of the general reserve fund, enterprise expansion fund, statutory surplus reserve and discretionary surplus fund are restricted to the offsetting of losses or increases the registered capital of the respective company. The staff bonus and welfare fund is a liability in nature and is restricted to fund payments of special bonus to employees and for the collective welfare of employees. All these reserves are not allowed to be transferred to the company in terms of cash dividends, loans or advances, nor can they be distributed except under liquidation.

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), to clarify the principles of recognizing revenue and create common revenue recognition guidance for U.S. GAAP and International Financial Reporting Standards. An entity has the option to apply the provisions of ASU 2014-09 either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this standard recognized at the date of initial application. ASU 2014-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2017, and early adoption is permitted but not earlier than the original effective date of December 15, 2016. The new standard supersedes U.S. GAAP guidance on revenue recognition and requires the use of more estimates, judgements and additional disclosures.

The Group will adopt the new standard using the modified retrospective method on January 1, 2018 and has assessed the impact on revenue from customers. The Group's revenue from contracts with customers comprises of research and development projects in its Innovation Platform and sales of goods and services in its Commercial Platform operating segments. The Group expects the changes from applying the new guidance will primarily impact the Innovation Platform.

Innovation Platform—The Group has reviewed its research and development contracts and identified two contracts related to the Group's license and collaboration arrangements that will be impacted by the application of ASU 2014-09. The license and collaboration arrangements contain multiple performance obligations: (1) the license to the drug compound and (2) the research and development services for each specified treatment indication. The transaction price includes fixed and variable consideration in the form of upfront payment, research and development costs reimbursements, contingent milestone payments and sales-based royalties. The allocation of the transaction price to each performance obligation is based on the relative standalone selling price of each performance obligation. The Group has determined that control of the license to the drug compound was transferred as of the inception date of the collaboration agreements and consequently, amounts allocated to this performance obligation are recognized at a point in time. Conversely, control of the research and development services for each specified indication is transferred over time and amounts allocated to these performance obligations are recognized over time using cost inputs as a measure of progress. In addition, royalty revenues will be recognized as future sales occur as they meet the requirements for the sales-usage based royalty exception. The Group expects US\$1.1 million deferral of revenue as a cumulative adjustment to opening accumulated loss upon adoption.

Commercial Platform—For sales of goods and services, the Group has applied a portfolio approach to aggregate contracts into portfolios whose performance obligations do not differ materially from each

other. In its assessment of each portfolio, the Group has assessed the contracts under the new five-step model and does not expect a significant impact to the timing or amount of revenue recognition under the new guidance. Control of the goods passes to the customer when the goods are delivered, which matches the timing of revenue recognition under the Group's existing accounting policy.

The Group has applied updates to the new guidance in its assessment including ASU 2016-08, Principal versus Agent Considerations, ASU 2016-10, Identifying Performance Obligations and Licensing.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) ("ASU 2016-02"). The core principle of ASU 2016-02 is that a lessee should recognize the assets and liabilities that arise from leases. A lessee should recognize in the balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. ASU 2016-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2018. The Group expects to adopt the new standard using the modified retrospective method on January 1, 2019 with a retrospective adjustment to comparable periods presented starting from January 1, 2017. The Group is currently determining the potential impact ASU 2016-02 will have on the Group's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business ("ASU 2017-01"), which revises the definition of a business. To be considered a business, an acquisition would have to include an input and a substantive process that together significantly contribute to the ability to create outputs. To be a business without outputs, there will now need to be an organized workforce. ASU 2017-01 is effective for fiscal years and interim periods within those years beginning after December 15, 2018. The Group currently does not expect ASU 2017-01 to have a material impact on the Group's consolidated financial statements, but will apply the guidance upon adoption to business acquisitions, disposals and segment changes, if any.

In May 2017, the FASB issued ASU 2017-09, Scope of Modification Accounting (Topic 718) ("ASU 2017-09"), which provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under share-based payment accounting. The guidance clarifies that no new measurement date will be required if there is no change to the fair value, vesting conditions, and classification, and in effect simplifies the accounting for non-substantive changes to share-based payment awards. ASU 2017-09 is effective for fiscal years and interim periods within those years beginning after December 15, 2017. The Group shall apply the guidance upon adoption to share-based payment modifications, if any.

Other amendments that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Group's consolidated financial statements upon adoption.

#### 4. Fair Value Disclosures

The following table presents the Group's financial instruments by level within the fair value hierarchy:

	Fair Value Measurement Using			
	Level 1	Level 2	Level 3	Total
		(in US	S\$'000)	
As at December 31, 2017				
Cash and cash equivalents	85,265	_	_	85,265
Short-term investments	273,031	_	_	273,031
As at December 31, 2016				
Cash and cash equivalents	79,431	_	_	79,431
Short-term investments	24,270			24,270

Accounts receivable, other receivables, amounts due from related parties, accounts payable, other payables and amounts due to related parties are carried at cost, which approximates fair value due to the short-term nature of these financial instruments, and are therefore excluded from the above table. Bank borrowings are floating rate instruments and carried at amortized cost, which approximates their fair values, and are therefore excluded from the above table.

## 5. Cash and Cash Equivalents

	December 31,	
	2017	2016
	(in US	<b>\$</b> '000)
Cash at bank and on hand	30,018	31,218
Bank deposits maturing in three months or less (note (a))	55,247	48,213
	85,265	79,431
Denominated in:		
US\$(note (b))	66,381	65,509
RMB (note (b))	15,140	9,505
UK Pound Sterling ("£") (note (b))	295	408
Hong Kong dollar ("HK\$")	3,449	4,009
	85,265	79,431

#### Notes:

- (a) The weighted average effective interest rate on bank deposits for the years ended December 31, 2017 and 2016 was 1.06% and 0.58% per annum respectively (with maturity ranging from 7 to 90 days).
- (b) Certain cash and bank balances denominated in RMB, US\$ and £ were deposited with banks in the PRC. The conversion of these RMB, US\$ and £ denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

#### 6. Short-term Investments

	Decemb	ber 31,
	2017	2016
	(in US	\$'000)
Bank deposits maturing over three months (note)		
Denominated in:		
US\$	272,659	24,270
HK\$	372	
	273,031	24,270

## Note:

The weighted average effective interest rate on bank deposits for the years ended December 31, 2017 and 2016 was 1.32% and 0.71% per annum respectively (with maturity ranging from 91 to 183 days, and 91 to 186 days respectively).

## 7. Accounts Receivable—Third Parties

	Decemb	ber 31,
	2017	2016
	(in US	\$'000)
Accounts receivable, gross	38,668	43,532
Allowance for doubtful accounts	(258)	(2,720)
Accounts receivable, net	38,410	40,812

Substantially all the accounts receivable are denominated in RMB, US\$ and HK\$ and are due within one year from the end of the reporting periods. The carrying values of accounts receivable approximates their fair values due to their short-term maturities.

Movements on the allowance for doubtful accounts:

	2017	2016	2015
		(in US\$'000)	
As at January 1	2,720	3,127	1,793
Increase in allowance for doubtful accounts	242	29	1,408
Decrease in allowance due to subsequent collection	_	(237)	_
Write-off	(2,874)		_
Exchange difference	170	(199)	(74)
As at December 31	258	2,720	3,127

In December 2015, the Group recorded a provision amounting to approximately US\$1,322,000 which represented an outstanding balance due from a distributor. In January 2016, the Group terminated the distributor's exclusive distribution rights and in December 2017, the amount due was written off along with other allowance for doubtful accounts balances.

# 8. Other Receivables, Prepayments and Deposits

Other receivables, prepayments and deposits consisted of the following:

	December 31,	
	2017	2016
	(in US	\$'000)
Prepayments	2,565	699
Purchase rebates	284	238
Other service receivables	490	756
Deposits	932	620
Value-added tax receivables	5,436	1,380
Interest receivables	506	63
Others	1,083	558
	11,296	4,314

## 9. Inventories

Inventories, net of provision for excess and obsolete inventories, consisted of the following:

	Decer	nber 31,
	2017	2016
	(in U	(S\$'000)
Raw materials	314	660
Finished goods	_ 11,475	12,162
	11,789	12,822

Movements on the provision for excess and obsolete inventories are as follows:

	2017	2016	2015
	(i	n US\$'000)	
As at January 1	160	25	34
Increase in provision for excess and obsolete inventories	128	163	37
Decrease in provision due to subsequent sale or recovery	(144)	_	(33)
Write-off	(32)	(23)	(12)
Exchange difference	9	(5)	(1)
As at December 31	121	160	25

# 10. Property, Plant and Equipment

Property, plant and equipment consisted of the following:

Additions         —         301         155         1,374           Disposals         —         —         —         —         (394)           Transfers         —         2,050         2,321         (722)         (           Exchange differences         140         410         6         920           As at December 31, 2017         2,372         9,057         2,568         15,154           Accumulated depreciation           As at January 1, 2017         971         4,249         71         9,105	1,760 24,350 4,243 6,073 — (394) (3,649) — 204 1,680 2,558 31,709
As at January 1, 2017  As at January 1, 2017  Additions  — 301 155 1,374  Disposals  — — — — (394)  Transfers  — 2,050 2,321 (722) (  Exchange differences 140 410 6 920  As at December 31, 2017  Accumulated depreciation As at January 1, 2017  P11 4,249  Accumulated depreciation As at January 1, 2017  Accumulated depreciation	4,243 6,073 — (394) (3,649) — — — — — — — — — — — — — — — — — — —
Additions         —         301         155         1,374           Disposals         —         —         —         (394)           Transfers         —         2,050         2,321         (722)         (           Exchange differences         140         410         6         920           As at December 31, 2017         2,372         9,057         2,568         15,154           Accumulated depreciation         As at January 1, 2017         971         4,249         71         9,105	$ \begin{array}{ccc}  & & (394) \\ (3,649) & & - \\ 204 & & 1,680 \end{array} $
Transfers         —         2,050         2,321         (722)         (722)           Exchange differences         140         410         6         920           As at December 31, 2017         2,372         9,057         2,568         15,154           Accumulated depreciation           As at January 1, 2017         971         4,249         71         9,105	(3,649) — 204 1,680
Exchange differences       140       410       6       920         As at December 31, 2017       2,372       9,057       2,568       15,154         Accumulated depreciation         As at January 1, 2017       971       4,249       71       9,105	204 1,680
As at December 31, 2017 2,372 9,057 2,568 15,154  Accumulated depreciation As at January 1, 2017 971 4,249 71 9,105	
Accumulated depreciation As at January 1, 2017  971  4,249 71  9,105	2,558 31,709
As at January 1, 2017 971 4,249 71 9,105	
Danier 105 702 100 1441	— 14,396
Depreciation 105 763 169 1,441	2,478
Disposals — — — (337)	- (337)
Transfers — — 255 (255)	
Exchange differences 65 284 4 599	<u> </u>
As at December 31, 2017 1,141 5,296 499 10,553	<b>—</b> 17,489
Net book value	
As at December 31, 2017 1,231 3,761 2,069 4,601	2,558 14,220
Furniture and fixtures, other Plant equipment Leasehold and and motor Construing Buildings improvements equipment vehicles in pro-	
(in US\$'000) Cost	
As at January 1, 2016 2,392 5,989 88 12,806	567 21,842
	2,132 4,327
Disposals — (12) — (248)	— (260)
Transfers — — 886	(886) —
Exchange differences (160) (423) (2) (921)	(53) (1,559)
As at December 31, 2016 2,232 6,296 86 13,976	1,760 24,350
Accumulated depreciation	— 13,335
Accumulated depreciation As at January 1, 2016 932 3.549 70 8,784	
	- 2,239
As at January 1, 2016 932 3,549 70 8,784	
As at January 1, 2016 932 3,549 70 8,784 Depreciation 106 977 3 1,153	2,239
As at January 1, 2016 932 3,549 70 8,784  Depreciation 106 977 3 1,153  Disposals — (12) — (218)	- 2,239 - (230)
As at January 1, 2016 932 3,549 70 8,784  Depreciation 106 977 3 1,153  Disposals — (12) — (218)  Exchange differences (67) (265) (2) (614)	- 2,239 - (230) - (948)

Depreciation for the year ended December 31, 2015 was US\$1,908,000.

## 11. Investments in Equity Investees

Investments in equity investees consisted of the following:

	Decen	nber 31,
	2017	2016
	(in U	S\$'000)
HBYS	55,308	63,536
SHPL	69,417	77,939
NSPL	19,201	16,806
Other	311	225
	144,237	158,506

Particulars regarding the principal equity investees are disclosed in Note 2. All of the equity investees are private companies and there are no quoted market prices available for their shares.

Summarized financial information for the significant equity investees HBYS, SHPL and NSPL is as follows:

## (i) Summarized balance sheets

		Commercia	l Platform		Innova Platfo		
	Consumer Health HBYS		Prescription SHI		Drug R&D NSPL		
	Decemb	per 31,	Decemb	er 31,	December 31,		
	2017	2016	2017	2016	2017	2016	
			(in US	6'000)			
Current assets	101,570	123,181	129,535	146,350	9,640	5,393	
Non-current assets	107,226	98,554	103,477	97,656	30,000	30,000	
Current liabilities	(75,787)	(70,218)	(91,665)	(86,946)	(1,239)	(1,782)	
Non-current liabilities	(18,748)	(18,148)	(8,616)	(6,926)	` <u> </u>	<u> </u>	
Net assets	114,261	133,369	132,731	150,134	38,401	33,611	
Non-controlling interests	(3,645)	(6,297)					
	110,616	127,072	132,731	150,134	38,401	33,611	

## (ii) Summarized statements of operations

	Commercial Platform							Innovation Platform			
	Con	nsumer Hea HBYS							a))		
	Year Er	nded Decem	ber 31,	Year Ended December 31,			Year End	Year Ended December 31			
	2017	2016	2016 2015		7 2016 2015		2017	2016	2015		
				(	in US\$'000)				<u> </u>		
Revenue	227,422	224,131	211,603	244,557	222,368	181,140	_	_	_		
Gross profit	91,458	89,355	91,461	175,965	158,131	127,608	_	_	_		
Depreciation and											
amortization	(4,985)	(2,958)	(3,274)	(6,942)	(3,526)	(2,765)	_	_	_		
Interest income	220	238	628	757	565	306	_	_	_		
Finance cost	(117)	(123)	(158)	_	_	_	_	_	_		
Profit/(loss) before											
taxation	24,434	23,759	25,164	66,497	148,144	37,401	(9,210)	(8,482)	(7,552)		
Income tax expense	(= ===)	(= -= 1)	(* 0.40)	/40 0 <b>=</b> 1\	/==	(5.00.1)					
(note (b))	(3,629)	(3,631)	(3,948)	(10,874)	(27,645)	(6,094)					
Net income/(loss)	20,805	20,128	21,216	55,623	120,499	31,307	(9,210)	(8,482)	(7,552)		
Non-controlling interests	(29)	248	160	_	_	_			_		
Net income/(loss) attributable to the shareholders of equity					100 10-		(0.210)	(0.402)	<b>(2.2.5</b> )		
investee	20,776	20,376	21,376	55,623	120,499	31,307	(9,210)	(8,482)	(7,552)		

#### Notes:

- (a) NSPL only incurred research and development expenses in the periods presented.
- (b) HBYS and SHPL have been successful in their respective applications to renew the High and New Technology Enterprise ("HNTE") status. Accordingly, the companies were eligible to use a preferential income tax rate of 15% for the years ended December 31, 2017, 2016 and 2015.

For the years ended December 31, 2017, 2016 and 2015, other immaterial equity investees had net income of approximately US\$117,000, US\$95,000 and US\$12,000 respectively.

#### (iii) Reconciliation of summarized financial information

Reconciliation of the summarized financial information presented to the carrying amount of investments in equity investees is as follows:

	Commercial Platform					Innovation Platform			
	Consumer Health HBYS			Prescription Drugs SHPL			Drug R&D NSPL		
	2017	2016	2015	2017	2016	2015	2017	2016	2015
				(i	n US\$'000	)			
Opening net assets after non-controlling interests as at									
January 1	127,072	121,523	111,506	150,134	93,263	71,906	33,611	18,093	25,645
Net income/(loss) attributable to the shareholders of equity investee	20,776	20,376	21,376	55,623	120,499	31,307	(9,210)	(8,482)	(7,552)
Dividends declared	(45,128)	(6,000)	(6,410)	(81,299)	(55,057)	(6,410)	_	_	_
Other comprehensive income/(loss)	7,896	(8,827)	(4,949)	8,273	(8,571)	(3,540)	_	_	_
Investments	_	` —	` —	_		<u> </u>	14,000	10,000	_
Capitalization of loans	_	_	_	_	_	_	_	14,000	_
Closing net assets after non-controlling interests as at									
December 31	110,616	127,072	121,523	132,731	150,134	93,263	38,401	33,611	18,093
Group's share of net assets	55,308	63,536	60,762	66,365	75,067	46,632	19,201	16,806	9,046
Goodwill			_	3,052	2,872	3,077	´ —	_	_
Carrying amount of investments as at December 31	55,308	63,536	60,762	69,417	77,939	49,709	19,201	16,806	9,046

The equity investees had the following lease commitments and capital commitments:

(a) The equity investees lease various factories and offices under non-cancellable operating lease agreements. Future aggregate minimum payments under non-cancellable operating leases as from the dates indicated are as follows:

	Decemb	er 31,
	2017	2016
	(in US	\$'000)
Not later than 1 year	1,282	1,511
Between 1 to 2 years	400	1,184
Between 2 to 3 years	151	_
Between 3 to 4 years	141	_
Between 4 to 5 years	47	
Total minimum lease payments	2,021	2,695

## (b) Capital commitments

The equity investees had the following capital commitments:

	Decen	ıber 31,
	2017	2016
	(in U	S\$'000)
Property, plant and equipment		
Contracted but not provided for	1,034	6,162

## 12. Accounts Payable

	Decemb	oer 31,
	2017	2016
	(in US	\$'000)
Accounts payable—third parties	17,095	30,383
Accounts payable—non-controlling shareholders of subsidiaries	7,250	5,136
Accounts payable—related party (Note 22 (ii))	20	19
	24,365	35,538

Substantially all the accounts payable are denominated in RMB and US\$ and due within one year from the end of the reporting period. The carrying values of accounts payable approximate their fair values due to their short-term maturities.

#### 13. Other Payables, Accruals and Advance Receipts

Other payables, accruals and advance receipts consisted of the following:

	December 31,	
	2017	2016
	(in US	\$'000)
Accrued salaries and benefits	9,295	7,057
Accrued research and development expenses	14,613	11,771
Accrued selling and marketing expenses	4,121	4,340
Accrued administrative and other general expenses	4,729	4,078
Deferred government incentives	1,790	1,755
Loan from a non-controlling shareholder of a subsidiary		
(Note 22 (iv))	1,550	_
Payments in advance from customers	1,282	899
Others	3,573	1,816
	40,953	31,716

## 14. Bank Borrowings

Bank borrowings consisted of the following:

	Decem	ber 31,
	2017	2016
	(in US	S\$'000)
Current	29,987	19,957
Non-current		26,830
	29,987	46,787

The weighted average interest rate for outstanding bank borrowings for the years ended December 31, 2017, 2016 and 2015 was 1.90%, 1.52% and 1.39% per annum respectively. In addition, the Group incurred guarantee fees of US\$320,000, US\$471,000 and US\$471,000 respectively for the years ended December 31, 2017, 2016 and 2015, which was 0.76%, 0.94% and 0.95% per annum respectively of the weighted average outstanding bank borrowings. The carrying amounts of the Group's bank borrowings are all denominated in HK\$.

## 3-year term loan and 18-month revolving loan facilities

In November 2017, the Group through its subsidiary, entered into a facility agreement with a bank for the provision of unsecured credit facilities in the aggregate amount of HK\$400,000,000 (US\$51,282,000). The credit facilities include (i) a HK\$210,000,000 (US\$26,923,000) 3-year term loan facility and (ii) a HK\$190,000,000 (US\$24,359,000) 18-month revolving loan facility. The term loan bears interest at 1.50% over the Hong Kong Interbank Offered Rate ("HIBOR") per annum. The revolving loan facility bears interest at 1.25% over HIBOR per annum. As at December 31, 2017, no amounts have been drawn from the term loan or the revolving loan facilities. These credit facilities are guaranteed by the Company.

In December 2011, the Group through its subsidiary, entered into a three-year term loan with the same bank above in the aggregate principal amount of HK\$210,000,000 (US\$26,923,000). The term loan bears interest at 1.50% over the HIBOR per annum. In June 2014, the term loan was refinanced into a four-year term loan due June 2018 which bears interest at 1.35% over the HIBOR per annum. The loan was fully repaid in two installments of HK\$180,000,000 (US\$23,077,000) and HK\$30,000,000 (US\$3,846,000) in August 2017 and November 2017 respectively. The term loan was unsecured and

guaranteed by Hutchison Whampoa Limited, an indirect subsidiary of CK Hutchison. An annual fee was paid to Hutchison Whampoa Limited for the guarantee (Note 22(i)).

## 18-month term loan and revolving loan facilities

In February 2017, the Group through its subsidiary, entered into two separate facility agreements with banks for the provision of unsecured credit facilities in the aggregate amount of HK\$546,000,000 (US\$70,000,000). The first credit facility includes (i) a HK\$156,000,000 (US\$20,000,000) term loan facility and (ii) a HK\$195,000,000 (US\$25,000,000) revolving loan facility, both with a term of 18 months and an annual interest rate of 1.25% over HIBOR. The term loan was drawn from the first credit facility in March 2017 and is due in August 2018. The second credit facility includes (i) a HK\$78,000,000 (US\$10,000,000) term loan facility and (ii) a HK\$117,000,000 (US\$15,000,000) revolving loan facility, both with a term of 18 months and an annual interest rate of 1.25% over HIBOR. The term loan was drawn from the second credit facility in August 2017 and is due in August 2018. Accordingly, the term loans are recorded as short-term bank borrowings as at December 31, 2017. No amounts have been drawn from the revolving loan facilities. These credit facilities are guaranteed by the Company.

In March 2017, the Group repaid the HK\$156,000,000 (US\$20,000,000) term loan facility with the same banks above, which was part of the unsecured credit facilities in the aggregate amount of HK\$468,000,000 (US\$60,000,000) entered in February 2016. These unsecured credit facilities have been terminated.

## 3-year revolving loan facility

In November 2015, the Group through its subsidiary renewed a three year revolving loan facility with a bank in the aggregate amount of HK\$234,000,000 (US\$30,000,000) with an annual interest rate of 1.25% over HIBOR. This facility will expire in November 2018. In February 2017, HK\$20,000,000 (US\$2,564,000) was drawn from this facility and the amount was fully repaid in March 2017. As at December 31, 2017 and 2016, there were no amounts due under this loan.

The Group's bank borrowings are repayable as from the dates indicated as follows:

	Decen	nber 31,
	2017	2016
	(in U	S\$'000)
Not later than 1 year	30,000	20,000
Between 1 to 2 years		26,923
	30,000	46,923

As at December 31, 2017 and 2016, the Group had unutilized bank borrowing facilities of HK\$946,000,000 (US\$121,282,000) and HK\$546,000,000 (US\$70,000,000) respectively.

#### 15. Commitments and Contingencies

#### (i) Lease commitments

The Group leases various factories and offices under non-cancellable operating lease agreements. Future aggregate minimum payments under non-cancellable operating leases as from the dates indicated as follows:

	Decemb	per 31,
	2017	2016
	(in US	\$'000)
Not later than 1 year	3,330	1,711
Between 1 to 2 years	2,875	1,383
Between 2 to 3 years	2,132	1,053
Between 3 to 4 years	345	597
Between 4 to 5 years	161	108
Later than 5 years	17	45
Total minimum lease payments	8,860	4,897

## (ii) Capital commitments

The Group had the following capital commitments as from the dates indicated as follows:

	Decem	ber 31,
	2017	2016
	(in US	S\$'000)
Property, plant and equipment		
Contracted but not provided for	<u>161</u>	2,545

In addition, the Group has also undertaken to provide the necessary additional funds for NSPL to finance its ongoing operations.

## 16. Redeemable Non-controlling Interests

As at December 31, 2017 and 2016, no redeemable non-controlling interests were outstanding.

In November and December 2010, the Company and HMHL, entered into subscription and shareholders' agreements ("SSAs") with Mitsui & Co., Ltd. ("Mitsui") and SBCVC Fund III Company Limited ("SBCVC") (collectively, the "preferred shareholders"), whereby HMHL issued 7,390,029 redeemable convertible preferred shares ("Preferred Shares") for an aggregate consideration of US\$20.1 million. The Preferred Shares on an as-if-converted basis represented approximately 19.76% of the aggregate issued and outstanding share capital of HMHL on the closing date.

In October 2012, the Company repurchased all 2,815,249 Preferred Shares from SBCVC. The remaining 4,574,780 Preferred Shares of US\$12.5 million held by Mitsui represented approximately 12.24% of HMHL on a fully diluted basis.

In May and June 2014, the Company and HMHL further entered into two subscription agreements with Mitsui, whereby HMHL issued a total of 672,713 HMHL's Preferred Shares to Mitsui and 4,825,418 HMHL's ordinary shares to the Company for an aggregate consideration of US\$25.0 million, after which Mitsui's interest in HMHL remained at 12.24% on a fully diluted basis.

On July 23, 2015, the Company entered into a subscription agreement with Mitsui under which the Company issued 3,214,404 new ordinary shares of the Company valued at approximately US\$84.0 million in exchange for the Preferred Shares held by Mitsui with carrying value of US\$84.0 million (including

accretion adjustment up to July 23, 2015). The transaction was completed on July 23, 2015 and as a result of this transaction, Mitsui held approximately 5.69% of the enlarged share capital of the Company at that time. The outstanding balance of redeemable non-controlling interests was extinguished with the corresponding increase in the Company's shares and additional paid-in capital.

## Accounting for preferred shares

The Preferred Shares were redeemable upon occurrence of an event that is not solely within the control of the issuer. Accordingly, the Preferred Shares were recorded and accounted for as redeemable non-controlling interests outside of permanent equity in the Group's consolidated balance sheets. The Group recorded accretion when it was probable that the Preferred Shares will become redeemable. The accretion, which increases the carrying value of the redeemable non-controlling interests, was recorded against retained earnings, or in the absence of retained earnings, by recording against the additional paid-in capital. During the year ended December 31, 2015, HMHL recorded an accretion of US\$43,001,000 to the Preferred Shares based on such preferred shareholder's share of the estimated valuation of HMHL.

## 17. Ordinary Shares

The Company is authorized to issue 75,000,000 ordinary shares.

On March 17, 2016, the Company's ADS, each representing one-half of one ordinary share, commenced trading on the Nasdaq Global Select Market. Concurrently, the Company issued 3,750,000 ordinary shares in the form of 7,500,000 ADS for gross proceeds of US\$101.3 million. On April 13, 2016, the Company issued an additional 330,000 ordinary shares in the form of 660,000 ADS for gross proceeds of US\$8.9 million. Issuance costs totaled US\$14.2 million, of which US\$12.9 million and US\$1.3 million were paid in the years ended December 31, 2016 and 2015 respectively.

In October 2017, the Company issued 5,684,905 ordinary shares in the form of 11,369,810 ADS for gross proceeds of US\$301.3 million. Issuance costs totaled US\$8.6 million.

A summary of ordinary shares transactions (in thousands) is as follows:

	2017	2016	2015
As at January 1	60,706	56,533	53,076
Public offering	5,685	4,080	_
Share option exercises	56	93	243
Exchange of redeemable non-controlling interest			
(Note 16)			3,214
As at December 31	66,447	60,706	56,533

Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors of the Company.

## 18. Share-based Compensation

### (i) Share-based Compensation of the Company

The Company conditionally adopted a share option scheme on June 4, 2005 (as amended on March 21, 2007) and such scheme has a term of 10 years. It expired in 2016 and no further share options can be granted. Another share option scheme was conditionally adopted on April 24, 2015 (the "HCML Share Option Scheme"). Pursuant to the HCML Share Option Scheme, the Board of Directors of the Company may, at its discretion, offer any employees and directors (including Executive and Non-executive

Directors but excluding Independent Non-executive Directors) of the Company, holding companies of the Company and any of their subsidiaries or affiliates, and subsidiaries or affiliates of the Company share options to subscribe for shares of the Company.

The aggregate number of shares issuable under the HCML Share Option Scheme is 2,425,597 ordinary shares. The aggregate number of shares issuable under the prior share option scheme which expired in 2016 is 282,726 ordinary shares. As at December 31, 2017, the number of shares authorized but unissued was 8,552,963 ordinary shares.

Share options granted are generally subject to a three-year or four-year vesting schedule, depending on the nature and the purpose of the grant. Share options subject to three-year vesting schedule, in general, vest 33.3% upon the first anniversary of the vesting commencement date as defined in the grant letter, and 33.3% every subsequent year. Share options subject to the four-year vesting schedule, in general, vest 25% upon the first anniversary of the vesting commencement date as defined in the grant letter, and 25% every subsequent year. However, certain share option grants may have a different vesting schedule as approved by the Board of Directors of the Company. No outstanding share options will be exercisable or subject to vesting after the expiry of a maximum of eight to ten years from the date of grant.

On June 15, 2016, 1,187,372 share options of a subsidiary were cancelled with the consent of the relevant eligible employees in exchange for 593,686 new share options of the Company (Note 18(ii)). This was accounted for as a modification of the original share options granted which did not result in any incremental fair value to the Group.

A summary of the Company's share option activity and related information is as follows:

Number of share options	Weighted-average exercise price in £ per share	Weighted-average remaining contractual life (years)	Aggregate intrinsic value (in £'000)
684,403	4.67		
_	_		
(242,038)	3.77		
	_		
442,365	5.16	6.53	10,061
693,686	19.70		
(92,705)	3.54		
( ' /	6.10		
/ /	15.00	6.77	7,900
	31.05		
\ ' /			
	6.10		
1,126,412	17.69	6.29	43,158
333,393	4.85	6.05	7,685
291,015	4.67	5.77	6,762
1,039,596	15.00	6.77	7,900
767,376	14.64	6.66	6,106
1,126,412	17.69	6.29	43,158
951,412	15.52	5.81	38,508
	share options  684,403  — (242,038)  — 442,365 693,686 (92,705) (3,750) 1,039,596 150,000 (56,309) (6,875) 1,126,412 333,393 291,015 1,039,596 767,376 1,126,412	share options         exercise price in £ per share           684,403         4.67           —         —           (242,038)         3.77           —         —           442,365         5.16           693,686         19.70           (92,705)         3.54           (3,750)         6.10           1,039,596         15.00           150,000         31.05           (56,309)         5.16           (6,875)         6.10           1,126,412         17.69           333,393         4.85           291,015         4.67           1,039,596         15.00           767,376         14.64           1,126,412         17.69	Number of share options         Weighted-average exercise price in £ per share         remaining contractual life (years)           684,403         4.67           —         —           (242,038)         3.77           —         —           442,365         5.16         6.53           693,686         19.70         (92,705)         3.54           (3,750)         6.10         1,039,596         15.00         6.77           150,000         31.05         (56,309)         5.16         6.29           (6,875)         6.10         1,126,412         17.69         6.29           333,393         4.85         6.05           291,015         4.67         5.77           1,039,596         15.00         6.77           767,376         14.64         6.66           1,126,412         17.69         6.29

The Company uses the Polynomial model to estimate the fair value of share option awards using various assumptions that require management to apply judgment and make estimates, including:

## **Volatility**

The Company calculated its expected volatility with reference to the historical volatility prior to the issuances of share options.

## Risk-free Rate

The risk-free interest rates used in the Polynomial model are with reference to the sovereign yield of the United Kingdom because the Company's ordinary shares are currently listed on AIM and denominated in £.

#### Dividends

The Company has not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore uses an expected dividend yield of zero in the Polynomial model.

In determining the fair value of share options granted, the following assumptions were used in the Polynomial model for awards granted in the periods indicated:

	Grant date			
	June 24, 2011	December 20, 2013	June 15, 2016	March 27, 2017
Value of each share option (in £ per share)	1.84	3.15	8.99	12.69
Significant inputs into the valuation model:				
Exercise price (in £ per share)	4.41	6.10	19.70	31.05
Share price at effective date of grant (in £ per share)	4.33	6.10	19.70	31.05
Expected volatility	46.6%	36.0%	39.0%	36.3%
Risk-free interest rate	3.13%	3.16%	1.00%	1.17%
Contractual life of share options	10 years	10 years	8 years	10 years
Expected dividend yield	0%	0%	0%	0%

The following table summarizes the Company's share option values:

	Year Ended December 31		iber 31,
	2017	2016	2015
Weighted-average grant-date fair value of share options			
granted during the period (in £ per share)	12.69	8.99	_
Total intrinsic value of share options exercised in US\$'000	2,290	1,907	5,020

## Share-based Compensation Expense

The Group recognizes compensation expense for only the portion of options expected to vest, on a graded vesting approach over the requisite service period. The following table presents share-based compensation expense included in the Group's consolidated statements of operations:

	Year I	Year Ended December 31,		
	2017	2016	2015	
		(in US\$'000)		
Research and development expenses	1,284	1,278	74	
Administrative expenses			14	
	1,284	1,278	88	

As at December 31, 2017, the total unrecognized compensation cost was US\$1,539,000, and will be recognized on a graded vesting approach over the weighted-average remaining service period of 3.1 years.

Cash received from share option exercises under the share option plan for the years ended December 31, 2017, 2016 and 2015 was approximately US\$380,000, US\$426,000 and US\$1,374,000 respectively.

The Company will issue new shares to satisfy share option exercises.

## (ii) Share-based Compensation of a subsidiary

HMHL adopted a share option scheme on August 6, 2008 (as amended on April 15, 2011) and such scheme has a term of 6 years. It expired in 2014 and no further share options can be granted. Another share option scheme was adopted on December 17, 2014 (the "HMHL Share Option Scheme"). Pursuant to the HMHL Share Option Scheme, any employee or director of HMHL and any of its holding company, subsidiaries and affiliates is eligible to participate in the HMHL Share Option Scheme subject to the discretion of the board of directors of HMHL.

The aggregate number of shares issuable under the HMHL Share Option Scheme is 2,144,408 ordinary shares. As at December 31, 2017, the number of shares authorized but unissued was 157,111,839 ordinary shares of HMHL.

Share options granted are generally subject to a four-year vesting schedule, depending on the nature and the purpose of the grant. Share options subject to the four-year vesting schedule, in general, vest 25% upon the first anniversary of the vesting commencement date as defined in the grant letter, and 25% every subsequent year. No outstanding share options will be exercisable or subject to vesting after the expiry of a maximum of six or nine years from the date of grant.

On December 20, 2013, 2,485,189 share options were cancelled with the consent of the relevant eligible employees in exchange for new share options of the Company vesting over a period of four years and/or cash consideration payable over a period of four years. For the share options in exchange for new share options under HCML Share Option Scheme, this was accounted for as a modification of the original share options which did not result in any incremental fair value to the Group. For the share options in exchange for cash consideration, this was accounted for as a modification in classification that changed the award's classification from equity-settled to a liability.

A liability has been recognized on the modification date taking into account the requisite service period that has been provided by the employee at the modification date. As at December 31, 2017 and 2016, US\$0.2 million and US\$1.4 million have been recognized in other payables respectively.

On June 15, 2016, 1,187,372 share options pursuant to the HMHL Share Option Schemes were cancelled with the consent of the relevant eligible employees in exchange for 593,686 new share options of the Company pursuant to the HCML Share Option Schemes. This was accounted for as a modification of the original share options granted which did not result in any incremental fair value to the Group.

A summary of the HMHL's share option activity and related information is as follows (with no activity for the year ended December 31, 2017):

	Number of share options	Weighted-average exercise price in £ per share	Weighted-average remaining contractual life (years)	Aggregate intrinsic value (in £'000)
Outstanding at January 1, 2015	1,211,772	7.71		
Granted	_	_		
Exercised	(24,400)	2.34		
Cancelled	_	_		
Outstanding at December 31, 2015	1,187,372	7.82	7.97	32,292
Granted	_	_		
Exercised	_	_		
Cancelled	(1,187,372)	7.82		
Outstanding at December 31, 2016 and 2017		_	_	
Vested and expected to vest at December 31,				
2015	759,918	7.82	7.97	20,667
Vested and exercisable at December 31, 2015	593,686	7.82	7.97	16,146
Vested and expected to vest at December 31,				
2016 and 2017	_	_	_	_
Vested and exercisable at December 31, 2016 and 2017	_	_	_	_

#### Share-based Compensation Expense

The subsidiary recognizes compensation expense for only the portion of options expected to vest, on a graded vesting approach over the requisite service period. The following table presents share-based compensation expense included in the Group's consolidated statements of operations:

Year En
2017
(i
32
2017

As at December 31, 2017, the total unrecognized compensation cost was nil.

Cash received from option exercises under the share option plan for the year ended December 31, 2015 was US\$57,000.

## (iii) LTIP

The Company grants awards under the LTIP to participating directors and employees, giving them a conditional right to receive ordinary shares of the Company or the equivalent ADS (collectively the "Awarded Shares") to be purchased by the Trustee up to a cash amount. Vesting will depend upon continued employment of the award holder with the Group and will otherwise be at the discretion of the Board of Directors of the Company. Additionally, some awards are subject to change based on annual performance targets prior to their determination date.

## LTIP awards prior to the determination date

Performance targets vary by award, and may include targets for shareholder returns, free cash flows, revenues, net profit after taxes and the achievement of clinical and regulatory milestones. As the extent of achievement of the performance targets is uncertain prior to the determination date, a probability based

on management's assessment on the achievement of the performance target has been assigned to calculate the amount to be recognized as an expense over the requisite period with a corresponding entry to liability.

## LTIP awards after the determination date

Upon the determination date, the Company will pay a determined monetary amount, up to the maximum cash amount based on the actual achievement of the performance target specified in the award, to the Trustee to purchase the Awarded Shares. Any cumulative compensation expense previously recognized as a liability will be transferred to additional paid-in capital, as an equity-settled award. If the performance target is not achieved, no Awarded Shares of the Company will be purchased and the amount previously recorded in the liability will be reversed through profit or loss.

Granted awards under the LTIP are as follows:

On December 15, 2017, the Company granted awards up to a maximum cash amount per annum of US\$0.5 million that stipulated annual performance targets. Shares under such LTIP awards will cover each financial year from 2018 to 2019. The annual performance target determination date is the date of the announcement of the Group's annual results for the covered financial year and vesting occurs two business days after the announcement of the Group's annual results for the financial year falling two years after the covered financial year to which the LTIP award relates.

On March 15, 2017 and August 2, 2017, the Company granted awards up to a maximum cash amount per annum of US\$6.0 million that stipulated annual performance targets. Shares under such LTIP awards will cover each financial year from 2017 to 2019. The annual performance target determination date is the date of the announcement of the Group's annual results for the covered financial year and vesting occurs two business days after the announcement of the Group's annual results for the financial year falling two years after the covered financial year to which the LTIP award relates.

On March 15, 2017, the Company granted awards up to a maximum cash amount of US\$0.4 million in aggregate that did not stipulate performance targets. Shares under such LTIP awards will vest one business day after the publication date of the annual report for the 2017 financial year.

On March 24, 2016, the Company granted awards up to a maximum cash amount of US\$0.3 million in aggregate that do not stipulate performance targets. Shares under such LTIP awards are subject to the vesting schedule of 25% on each of the first, second, third and fourth anniversaries of the date of grant.

On October 19, 2015, the Company granted initial awards under the LTIP up to a maximum cash amount per annum of US\$1.8 million that stipulated annual performance targets. Shares under such LTIP awards will cover each financial year from 2014 to 2016. The annual performance target determination date is the date of the announcement of the Group's annual results for the covered financial year and vesting occurs one business day after the publication date of the annual report of the Company for the financial year falling two years after the covered financial year to which the LTIP award relates.

The Trustee has been set up solely for the purpose of purchasing and holding the Awarded Shares during the vesting period on behalf of the Group using funds provided by the Group. On the determination date, if any, the Company will determine the cash amount, based on the actual achievement of each annual performance target, for the Trustee to purchase the Awarded Shares. The Awarded Shares will then be held by the Trustee until they are vested.

The Trustee's assets include treasury shares and funds for additional treasury shares, trustee fees and expenses. As at December 31, 2017, the number of treasury shares (in the form of ordinary shares or ADS of the Company) purchased and held by the Trustee are as follows:

	Number of treasury shares	Cost in US\$'000
As at January 1, 2017	62,921	2,390
Purchased	35,095	1,367
Vested	(42,038)	(1,800)
As at December 31, 2017	55,978	1,957

Based on the actual achievement of performance targets for the 2017 financial year, the Group expects to purchase up to US\$5,621,000 of treasury shares in 2018.

For the year ended December 31, 2017, US\$1,800,000 and US\$79,000 of the LTIP awards have vested and been forfeited respectively.

The following table presents the share-based compensation expenses recognized under the LTIP awards:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Research and development expenses	1,894	850	156
Selling and administrative expenses	1,529	811	152
	3,423	1,661	308
Recorded with a corresponding credit to:			
Liability	2,336	345	75
Additional paid-in capital	1,087	1,316	233
	3,423	1,661	308

For the years ended December 31, 2017, 2016 and 2015, US\$451,000, US\$64,000 and nil was reclassified from liability to additional paid-in capital respectively upon LTIP awards reaching the determination date. As at December 31, 2017 and 2016, US\$2,241,000 and US\$356,000 was recorded as liability respectively for LTIP awards prior to the determination date.

As at December 31, 2017, the total unrecognized compensation cost was approximately US\$8,681,000, which considers expected performance targets and the amount expected to vest, and will be recognized over the requisite periods.

## 19. Revenue from License and Collaboration Agreements—Third Parties

	Year 1	Year Ended December 31,			
	2017	2016	2015		
		(in US\$'000)			
Milestone revenue	9,457	9,931	19,212		
Amortization of upfront payment	1,655	1,679	1,907		
Research and development services	15,203	14,834	22,941		
	26,315	26,444	44,060		

The revenue is mainly from license and collaboration agreements as follows:

## License and collaboration agreement with Eli Lilly

On October 8, 2013, the Group entered into a licensing, co-development and commercialization agreement in China with Eli Lilly ("Lilly") relating to fruquintinib, a targeted oncology therapy for the treatment of various types of solid tumors. Under the terms of the agreement, the Group is entitled to receive a series of payments of up to US\$86.5 million, including upfront payments and development and regulatory approval milestones. Should fruquintinib be successfully commercialized in China, the Group would receive tiered royalties based on certain percentages of net sales. Development costs after the first development milestone are shared between the Group and Lilly. Following execution of the agreement, the Group received a non-refundable, upfront payment of US\$6.5 million.

In addition, the Group also signed an option agreement which grants Lilly an exclusive option to expand the fruquintinib rights beyond Hong Kong and China. The option agreement further sets out certain milestone payments and royalty rates that apply in the event the option is exercised on a global basis. However, these are subject to further negotiation should the option be exercised on a specific territory basis as opposed to a global basis. The option was not considered to be a separate deliverable in the arrangement as it was not considered to be substantive. As at December 31, 2017, the option has not been exercised.

The license rights to fruquintinib, delivered at the inception of the arrangement, did not have standalone value apart from the other deliverables in the arrangement which include the development services, the participation in the joint steering committee and the manufacturing of active pharmaceutical ingredients during the development phase. The non-refundable upfront payment was deferred and is being recognized ratably over the development period. The Group recognizes milestone revenue relating to the deliverables in the agreement as a single unit of accounting using the milestone method.

Under the terms of this agreement, the Group recognized US\$4.5 million milestone revenue for the year ended December 31, 2017 in relation to the acceptance of a new drug application by the China Food and Drug Administration for fruquintinib as a treatment of patients with advanced colorectal cancer. For the year ended December 31, 2016, the Group did not recognize any milestone revenue in relation to this contract and for the year ended December 31, 2015, the Group recognized US\$19.2 million milestone revenues in relation to the achievement of the "proof of concept" milestone for two indications. The Group recognized US\$1.6 million, US\$1.7 million and US\$1.8 million revenue from amortization of the upfront payment during the years ended December 31, 2017, 2016 and 2015 respectively. In addition, the Group recognized US\$12.1 million, US\$12.1 million and US\$19.4 million revenue from research and development services for the years ended December 31, 2017, 2016 and 2015 respectively.

## License and collaboration agreement with AstraZeneca

On December 21, 2011, the Group and AstraZeneca ("AZ") entered into a global licensing, co-development, and commercialization agreement for savolitinib ("AZ Agreement"), a novel targeted therapy and a highly selective inhibitor of the c-Met receptor tyrosine kinase for the treatment of cancer. Under the terms of the agreement, development costs for savolitinib in China will be shared between the Group and AZ, with the Group continuing to lead the development in China. AZ will lead and pay for the development of savolitinib for the rest of the world. The Group received a non-refundable upfront payment of US\$20.0 million upon the signing of the agreement and may receive up to US\$120.0 million contingent upon the successful achievement of clinical development and first-sale milestones. The agreement also contains possible significant future commercial sale milestones and up to double-digit percentage royalties on net sales.

The license right to develop savolitinib in the rest of the world was delivered to AZ at the inception of the arrangement. Such license had stand-alone value apart from the other deliverables in the arrangement

which include the development of savolitinib in China and the participation in the joint steering committee. The non-refundable up-front payment was allocated to (a) the license to develop savolitinib in the rest of the world, which was recognized at inception and (b) the research and development services for which the amount allocated has been deferred and is being recognized ratably over the development period. The Group recognizes milestone revenue relating to the deliverables in the agreement as a single unit of accounting using the milestone method.

Under the terms of this agreement, the Group recognized US\$5.0 million milestone revenue for the year ended December 31, 2017 in relation to the Phase III initiation for the secondary indication, papillary renal cell carcinoma, and US\$9.9 million milestone revenue for the year ended December 31, 2016 in relation to the Phase IIb initiation for the primary indication, non-small cell lung cancer. For the year ended December 31, 2015, the Group did not recognize any milestone revenue in relation to this contract. The Group recognized less than US\$0.1 million revenue from amortization of the up-front payment for each of the years ended December 31, 2017, 2016 and 2015. In addition, the Group recognized US\$3.1 million, US\$2.7 million and US\$3.5 million revenue from research and development services for the years ended December 31, 2017, 2016 and 2015 respectively.

In August 2016, the Group entered into an amendment to the AZ Agreement. Under the terms of the amendment, the Group shall pay for up to a maximum of US\$50 million of phase III clinical trial costs related to developing savolitinib for papillary renal cell carcinoma. In return, AZ agrees to increase ex-China royalties on net sales by an additional 5% over the royalties stipulated in the original agreement until cumulative additional royalties paid reaches US\$250 million, after which the additional royalty decreases to 3% for 24 months and then 1.5% thereafter. The costs of the additional Phase III clinical trial costs shall be expensed to research and development expense as incurred. Under the current revenue recognition policy, future royalties shall be recognized as revenue from license and collaboration agreements—third parties as net sales occur. The amendment does not impact the original accounting for the AZ Agreement under the milestone method.

#### 20. Research and Development Expenses

Research and development expenses are summarized as follows:

	Year	Year Ended December 31,			
	2017	2016	2015		
		(in US\$'000)			
Clinical trial related costs	45,250	38,589	24,690		
Personnel compensation and related costs	24,848	21,698	17,339		
Other research and development expenses	_ 5,425	6,584	5,339		
	75,523	66,871	47,368		

## 21. Government Incentives

The Group receives government grants from the PRC Government (including the National level and Shanghai Municipal City). These grants are given in support of drug research and development activities and are conditional upon i) the Group spending a predetermined amount, regardless of success or failure of the research and development projects and ii) the achievement of certain stages of research and development projects being approved by the relevant PRC government authority. These government grants are subject to ongoing reporting and monitoring by the PRC Government over the period of the grant.

Government incentives, which are deferred and recognized in the consolidated statements of operations over the period necessary to match them with the costs that they are intended to compensate, are recognized in other payable, accruals and advance receipts (Note 13) and other non-current liabilities.

They are refundable to the PRC Government if the related research and development projects are suspended. For the years ended December 31, 2017, 2016 and 2015, the Group received government grants of US\$1,323,000, US\$1,872,000 and US\$4,898,000 respectively.

The government grants recorded as a reduction to research and development expenses for the years ended December 31, 2017, 2016 and 2015 were US\$876,000 US\$1,269,000 and US\$3,664,000 respectively.

## 22. Significant Transactions with Related Parties and Non-Controlling Shareholders of Subsidiaries

The Group has the following significant transactions with related parties and non-controlling shareholders of subsidiaries, which were carried out in the normal course of business at terms determined and agreed by the relevant parties.

## (i) Transactions with related parties:

	Year Ended December 31,			
	2017	2016	2015	
	(in US\$'000)			
Sales to:				
Indirect subsidiaries of CK Hutchison	8,486	9,794	8,074	
Revenue from research and development services:				
Equity investees	9,682	8,429	5,383	
Purchases from:				
Equity investees	1,182	280	3,701	
Rendering of marketing services from:				
Indirect subsidiaries of CK Hutchison	372	741	751	
An equity investee	10,195	8,401	5,093	
	10,567	9,142	5,844	
Rendering of management services from:				
Indirect subsidiaries of CK Hutchison	897	874	845	
Interest paid to:				
Immediate holding company	_	152	144	
An indirect subsidiary of CK Hutchison	132			
	132	152	144	
Guarantee fee on bank loan to:				
An indirect subsidiary of CK Hutchison	320	471	471	

#### (ii) Balances with related parties included in:

	December 31,	
	2017	2016
	(in US	\$'000)
Accounts receivable—related parties		
Indirect subsidiaries of CK Hutchison (note (a))	2,761	2,589
Equity investees (note (a))	1,099_	1,634
	3,860	4,223
Accounts payable		
An indirect subsidiary of CK Hutchison (note (a))	_	19
An equity investee (note (a))	20	_
	20	19
Amounts due from related parties		
An indirect subsidiary of CK Hutchison (note (a))	23	107
Equity investees (note (a))	893	1,029
Dividend receivable from an equity investee	7,628	
	8,544	1,136
Amounts due to related parties		
Immediate holding company (note (b))	_	2,086
An indirect subsidiary of CK Hutchison (note (b))	454	152
An equity investee (note (a))	6,567	3,070
	7,021	5,308
Other deferred income		
An equity investee (note (c))	1,648	1,771
Other non-current liabilities		
Immediate holding company (note (d))		6,000

#### Notes:

- (a) Balances with related parties are unsecured, interest-free and repayable on demand. The carrying values of balances with related parties approximate their fair values due to their short-term maturities.
- (b) Amounts due to immediate holding company and an indirect subsidiary of CK Hutchison are unsecured and interest-bearing. During the year ended December 31, 2017, amounts due to immediate holding company were assigned to an indirect subsidiary of CK Hutchison. As at December 31, 2017, approximately US\$454,000 (December 31, 2016: US\$2,238,000) of such balances are repayable within one year or repayable on demand.
- (c) Other deferred income represents amounts recognized from granting of promotion and marketing rights.
- (d) In December 2017, the Group repaid the amount due. As at December 31, 2016, this amount was recorded in non-current liabilities as it was repayable in equal installments of US\$3,000,000 in December 2018 and December 2019.

#### (iii) Transactions with non-controlling shareholders of subsidiaries:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Sales	13,307	12,274	6,196
Purchases	21,236	15,225	12,169
Interest expense	66	78	85
Dividend declared	1,594	564	590

#### (iv) Balances with non-controlling shareholders of subsidiaries included in:

	Decem	ber 31,
	2017	2016
	(in US	S\$'000)
Accounts receivable—third parties	1,846	
Accounts payable	7,250	5,136
Other payables, accruals and advance receipts		
Loan	1,550	
Interest payable	80	14
	1,630	14
Other non-current liabilities		
Loans	579	2,129

#### 23. Income Taxes

#### (i) Income tax expense

	Year	Year Ended December 31,			
	2017	2017 2016 (in US\$'000)			
Current tax					
HK (note (a))	572	520	150		
PRC (note (b))	782	458	415		
Deferred income tax	1,726	3,353	1,040		
Income tax expense	3,080	4,331	1,605		

#### Notes:

- (a) The Company, a subsidiary incorporated in the British Virgin Islands and its Hong Kong subsidiaries are subject to Hong Kong profits tax which has been provided for at the rate of 16.5% on the estimated assessable profits less estimated available tax losses in each entity.
- (b) Taxation in the PRC has been provided for at the applicable rate on the estimated assessable profits less estimated available tax losses, if any, in each entity. Under the PRC Enterprise Income Tax Law (the "EIT Law"), the standard enterprise income tax rate is 25%. In addition, the EIT Law provides for, among others, a preferential tax rate of 15% for companies which qualify as HNTE. HMPL qualifies as a HNTE up to December 31, 2019. Pursuant to the EIT law, a 10% withholding tax is levied on dividends declared by PRC

companies to their foreign investors. A lower withholding tax rate of 5% is applicable under the China-HK Tax Arrangement if direct foreign investors with at least 25% equity interest in the PRC companies are Hong Kong tax residents, and meet the conditions or requirements pursuant to the relevant PRC tax regulations regarding beneficial ownership. Since the equity holders of the major subsidiaries and equity investees of the Company are Hong Kong incorporated companies and Hong Kong tax residents, and meet the aforesaid conditions or requirements, the Company has used 5% to provide for deferred tax liabilities on retained earnings which are anticipated to be distributed. As at December 31, 2017 and 2016, the amounts accrued in deferred tax liabilities relating to withholding tax on dividends were determined on the basis that 100% of the distributable reserves of the major subsidiaries and equity investees operating in the PRC will be distributed as dividends.

The reconciliation of the Group's reported income tax expense to the theoretical tax amount that would arise using the tax rates of the Company against the Group's loss before income taxes and equity in earnings of equity investees is as follows:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Loss before income taxes and equity in earnings of equity investees	(53,536)	(47,356)	(10,540)
Tax calculated at the statutory tax rate of the Company	(8,833)	(7,814)	(1,739)
Tax effects of:			
Different tax rates available in different jurisdictions	2,531	453	(2,953)
Tax valuation allowance	11,410	9,886	6,601
Preferential tax deduction	(3,347)	(3,205)	(2,096)
Expenses not deductible for tax purposes	391	688	253
Utilization of previously unrecognized tax losses	(387)	(21)	(34)
Withholding tax on undistributed earnings of PRC entities	1,980	3,532	1,216
Others	(665)	812	357
Income tax expense	3,080	4,331	1,605

#### (ii) Deferred tax assets and liabilities

The significant components of deferred tax assets and liabilities are as follows:

	Decemb	er 31,
	2017	2016
	(in US\$	(2000)
Deferred tax assets		
Tax losses	31,028	20,145
Others	1,267	372
Total deferred tax assets	32,295	20,517
Less: Valuation allowance	(31,662)	(20,145)
Deferred tax assets	633	372
Deferred tax liabilities		
Undistributed earnings from PRC entities	4,332	5,230
Others	120	131
Deferred tax liabilities	4,452	5,361

As at December 31, 2017, all deferred tax assets and liabilities are classified as non-current after adopting ASU 2015-17. As at December 31, 2016, deferred tax assets and liabilities of US\$372,000 and US\$1,364,000 respectively were classified as current, with the remainder as non-current.

The significant components of deferred tax assets and liabilities are as follows:

	2017	2016	2015
		(in US'000)	
As at January 1	(4,989)	(3,473)	(2,842)
Utilization of previously recognized withholding tax on undistributed			
earnings	3,179	1,526	321
(Charged)/Credited to the consolidated statements of operations			
Withholding tax on undistributed earnings of PRC entities	(1,980)	(3,532)	(1,216)
Deferred tax on amortization of intangible assets	18	32	24
Deferred tax on provision for assets	236	147	152
Exchange differences	(283)	311	88
As at December 31	(3,819)	(4,989)	(3,473)

The deferred tax assets and liabilities are offset when there is a legally enforceable right to set off and when the deferred income taxes relate to the same fiscal authority.

The tax losses can be carried forward against future taxable income and will expire in the following years:

	Decem	ber 31,
	2017	2016
	(in US	S\$'000)
No expiry date	42,385	32,859
2017		3,651
2018	858	807
2019	4,261	4,012
2020	36,188	34,059
2021	50,494	53,194
2022	65,195	
	199,381	128,582

The Company believes that it is more likely than not that future operations will not generate sufficient taxable income to realize the benefit of the deferred tax assets. The Company's subsidiaries have had sustained tax losses, which will expire within five years if not utilized in the case of PRC subsidiaries, and which will not be utilized in the case of Hong Kong subsidiaries as they do not generate taxable profits. Accordingly, a valuation allowance has been recorded against the relevant deferred tax assets arising from the tax losses.

The table below summarizes changes in the deferred tax valuation allowance:

	2017	2016	2015
		(in US\$'000)	
As at January 1	20,145	11,393	7,455
Charged to consolidated statements of operations	11,410	9,886	6,601
Utilization of previously unrecognized tax losses	(387)	(21)	(34)
Write-off of expired tax losses	(558)		(1,493)
Others	(89)	(288)	(901)
Exchange differences	1,141	(825)	(235)
As at December 31	31,662	20,145	11,393

The Group recognizes interest and penalties, if any, under income tax payable on its consolidated balance sheets and under other expenses in its consolidated statements of operations. As at December 31, 2017 and 2016, the Group did not have any material unrecognized uncertain tax positions.

#### (iii) Income tax payable

	2017	2016	2015
		(in US\$'000)	
As at January 1	274	442	112
Current tax	1,354	978	565
Withholding tax upon dividend declaration from PRC entities	3,179	1,526	321
Tax paid	(3,836)	(2,664)	(510)
Exchange difference	8	(8)	(46)
As at December 31	979	274	442

#### 24. (Losses)/Earnings per Share

#### (i) Basic (losses)/earnings per share

Basic (losses)/earnings per share is calculated by dividing the net (loss)/income attributable to ordinary shareholders of the Company by the weighted average number of ordinary shares in issue during the year. Treasury shares held by the Trustee are excluded from the weighted average number of outstanding ordinary shares in issue for purposes of calculating basic (losses)/earnings per share.

	Year Ended December 31,		
	2017	2016	2015
Weighted average number of outstanding ordinary shares in issue	61,717,171	59,715,173	54,659,315
Net (loss)/income (US\$'000)	(22,963)	14,557	10,427
Net income attributable to non-controlling interests (US\$'000)	(3,774)	(2,859)	(2,434)
Accretion on redeemable non-controlling interests (US\$'000)			(43,001)
Net (loss)/income for the year attributable to ordinary shareholders of the Company (US\$'000)	(26,737)	11,698	(35,008)
(Losses)/earnings per share attributable to ordinary shareholders of the Company (US\$ per share)	(0.43)	0.20	(0.64)

#### (ii) Diluted (losses)/earnings per share

Diluted (losses)/earnings per share is calculated by dividing net (loss)/income attributable to ordinary shareholders of the Company, by the weighted average number of ordinary and dilutive ordinary share

equivalents outstanding during the year. Dilutive ordinary share equivalents include shares issuable upon the exercise or settlement of share-based awards issued by the Company and its subsidiaries using the treasury stock method.

	Year Ended December 31,		
	2017	2016	2015
Weighted average number of outstanding ordinary shares in issue	61,717,171	59,715,173	54,659,315
Adjustment for share options and LTIP	_	255,877	_
	61,717,171	59,971,050	54,659,315
Net (loss)/income for the year attributable to ordinary shareholders of the Company (US\$'000)	(26,737)	11,698	(35,008)
(Losses)/earnings per share attributable to ordinary shareholders of the Company (US\$ per share)	(0.43)	0.20	(0.64)

For the years ended December 31, 2017 and 2015, the share options and LTIP awards issued by the Company as well as the preferred shares issued by HMHL were not included in the calculation of diluted losses per share because of their anti-dilutive effect.

#### 25. Segment Reporting

The Group determines its operating segments from both business and geographic perspectives as follows:

- (i) Innovation Platform (Drug research and development ("Drug R&D")): focuses on discovering and developing innovative therapeutics in oncology and autoimmune diseases, and the provision of research and development services; and
- (ii) Commercial Platform: comprises of the manufacture, marketing and distribution of prescription and over-the-counter pharmaceuticals in the PRC as well as consumer health products through Hong Kong. The Commercial Platform is further segregated into two core business areas:
  - (a) Prescription Drugs: comprises the development, manufacture, distribution, marketing and sale of prescription pharmaceuticals; and
  - (b) Consumer Health: comprises the development, manufacture, distribution, marketing and sale of over-the-counter pharmaceuticals and consumer health products.

Innovation Platform and Prescription Drugs businesses under the Commercial Platform are primarily located in the PRC. The locations for Consumer Health business under the Commercial Platform are further segregated into the PRC and Hong Kong.

The performance of the reportable segments is assessed based on three measurements: (a) losses or earnings of subsidiaries before interest income, interest expense, income tax expenses and equity in earnings of equity investees, net of tax ("Adjusted (LBIT)/EBIT" or "Adjusted LBIT"), (b) equity in earnings of equity investees, net of tax and (c) operating (loss)/profit.

The segment information is as follows:

Voor	hahna	December	31	2017	

	Innovation Platform		Commercial	Platform			
	Drug R&D	Prescription Drugs	Consume	er Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				(in US\$'00	0)		
Revenue from external customers	35,997	166,435	9,858	28,913	205,206		241,203
Adjusted (LBIT)/EBIT	(47,503)	3,272	578	3,029	6,879	(12,677)	(53,301)
Interest income	64	37	13	13	63	1,093	1,220
Equity in earnings of equity investees, net of tax	(4,547)	27,812	10,388	_	38,200	_	33,653
Operating (loss)/profit	(51,986)	31,121	10,979	3,042	45,142	(11,584)	(18,428)
Interest expense		, <u> </u>	´ —	66	66	1,389	1,455
Income tax expense	26	934	(457)	509	986	2,068	3,080
Net (loss)/income attributable to ordinary shareholders of the							
Company	(51,880)	28,999	9,773	1,261	40,033	(14,890)	(26,737)
Depreciation/amortization	2,400	116	17	18	151	27	2,578
Additions to non-current assets (other than financial instrument and deferred	5.026	5.0	42	0	107	20	C 072
tax assets)	5,936	56	43	8	107	30	6,073

#### As at December 31, 2017

	Innovation Platform		Commercia	l Platform			
	Drug R&D	Prescription Drugs	Consum	er Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				(in US\$'000)			
Total assets	63,268	122,665	58,961	13,794	195,420	339,244	597,932
Property, plant and equipment	13,917	160	61	30	251	52	14,220
Leasehold land	1,261	_	_	_	_	_	1,261
Goodwill	_	2,901	407	_	3,308	_	3,308
Other intangible asset	_	430	_	_	430	_	430
Investments in equity investees	19,512	69,417	55,308	_	124,725	_	144,237

Year	ended	Decemb	er 31,	, 2016
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PRC   PRC   PRC   PRC   Hong   Subtoal   Unallocated   Total		Innovation Platform		Commercial	Platform			
PRC   PRC   PRC   Kong   Subtoal   Unallocated   Total				Consume	er Health			
Revenue from external customers         35,228         149,861         6,984         24,007         180,852         —         216,080           Adjusted (LBIT)/EBIT         (36,657)         2,377         (493)         1,852         3,736         (13,306)         (46,227)           Interest income         52         31         34         1         66         384         502           Equity in earnings of equity investees, net of tax         (4,232)         60,288         10,188         —         70,476         —         66,244           Operating (loss)/profit         (40,837)         62,696         9,729         1,853         74,278         (12,922)         20,519           Interest expense         —         —         —         79         79         1,552         1,631           Income tax expense         —         777         (497)         289         569         3,762         4,331           Net (loss)/income attributable to ordinary shareholders of the Company         (40,735)         61,120         8,384         833         70,337         (17,904)         11,698           Depreciation/amortization         2,176         102         3         19         124         41         2,341           Addition		PRC	PRC	PRC		Subtotal	Unallocated	Total
customers         35,228         149,861         6,984         24,007         180,852         —         216,080           Adjusted (LBIT)/EBIT         (36,657)         2,377         (493)         1,852         3,736         (13,306)         (46,227)           Interest income         52         31         34         1         66         384         502           Equity in earnings of equity investees, net of tax         (4,232)         60,288         10,188         —         70,476         —         66,244           Operating (loss)/profit         (40,837)         62,696         9,729         1,853         74,278         (12,922)         20,519           Income tax expense         —         —         —         79         79         1,552         1,631           Net (loss)/income attributable to ordinary shareholders of the Company         (40,735)         61,120         8,384         833         70,337         (17,904)         11,698           Depreciation/amortization         2,176         102         3         19         124         41         2,341           Additions to non-current assets (other than financial instrument and deferred         —         102         3         19         124         41         2,341 <th></th> <th></th> <th></th> <th></th> <th>(inUS\$'000</th> <th>))</th> <th></th> <th></th>					(inUS\$'000	))		
Interest income         52         31         34         1         66         384         502           Equity in earnings of equity investees, net of tax         (4,232)         60,288         10,188         —         70,476         —         66,244           Operating (loss)/profit         (40,837)         62,696         9,729         1,853         74,278         (12,922)         20,519           Interest expense         —         —         —         79         79         1,552         1,631           Income tax expense         —         777         (497)         289         569         3,762         4,331           Net (loss)/income attributable to ordinary shareholders of the Company         (40,735)         61,120         8,384         833         70,337         (17,904)         11,698           Depreciation/amortization         2,176         102         3         19         124         41         2,341           Additions to non-current assets (other than financial instrument and deferred         31         102         3         19         124         41         2,341		35,228	149,861	6,984	24,007	180,852		216,080
Interest income         52         31         34         1         66         384         502           Equity in earnings of equity investees, net of tax         (4,232)         60,288         10,188         —         70,476         —         66,244           Operating (loss)/profit         (40,837)         62,696         9,729         1,853         74,278         (12,922)         20,519           Interest expense         —         —         —         79         79         1,552         1,631           Income tax expense         —         777         (497)         289         569         3,762         4,331           Net (loss)/income attributable to ordinary shareholders of the Company         (40,735)         61,120         8,384         833         70,337         (17,904)         11,698           Depreciation/amortization         2,176         102         3         19         124         41         2,341           Additions to non-current assets (other than financial instrument and deferred         31         102         3         19         124         41         2,341	Adjusted (LBIT)/EBIT	(36,657)	2,377	(493)	1,852	3,736	(13,306)	(46,227)
investees, net of tax (4,232) 60,288 10,188 — 70,476 — 66,244  Operating (loss)/profit (40,837) 62,696 9,729 1,853 74,278 (12,922) 20,519  Interest expense — — — 79 79 1,552 1,631  Income tax expense — 777 (497) 289 569 3,762 4,331  Net (loss)/income attributable to ordinary shareholders of the Company (40,735) 61,120 8,384 833 70,337 (17,904) 11,698  Depreciation/amortization 2,176 102 3 19 124 41 2,341  Additions to non-current assets (other than financial instrument and deferred					1			
Interest expense         —         —         —         79         79         1,552         1,631           Income tax expense         —         777         (497)         289         569         3,762         4,331           Net (loss)/income attributable to ordinary shareholders of the Company         (40,735)         61,120         8,384         833         70,337         (17,904)         11,698           Depreciation/amortization         2,176         102         3         19         124         41         2,341           Additions to non-current assets (other than financial instrument and deferred         3         19         124         41         2,341		(4,232)	60,288	10,188	_	70,476	_	66,244
Interest expense         —         —         —         79         79         1,552         1,631           Income tax expense         —         777         (497)         289         569         3,762         4,331           Net (loss)/income attributable to ordinary shareholders of the Company         (40,735)         61,120         8,384         833         70,337         (17,904)         11,698           Depreciation/amortization         2,176         102         3         19         124         41         2,341           Additions to non-current assets (other than financial instrument and deferred         3         19         124         41         2,341	Operating (loss)/profit	(40,837)	62,696	9,729	1,853	74,278	(12,922)	20,519
Income tax expense         —         777         (497)         289         569         3,762         4,331           Net (loss)/income attributable to ordinary shareholders of the Company         (40,735)         61,120         8,384         833         70,337         (17,904)         11,698           Depreciation/amortization         2,176         102         3         19         124         41         2,341           Additions to non-current assets (other than financial instrument and deferred         3         19         124         41         2,341	1 0 ( )1		, <u> </u>	´ —	79		,	
attributable to ordinary shareholders of the Company (40,735) 61,120 8,384 833 70,337 (17,904) 11,698 Depreciation/amortization 2,176 102 3 19 124 41 2,341 Additions to non-current assets (other than financial instrument and deferred		_	777	(497)	289	569	3,762	4,331
Depreciation/amortization 2,176 102 3 19 124 41 2,341 Additions to non-current assets (other than financial instrument and deferred	attributable to ordinary shareholders of the	(40.725)	(1.120	0.204	922	70 227	(17.004)	11.600
Additions to non-current assets (other than financial instrument and deferred							,	
tax assets) <u>4,138</u> <u>67</u> <u>20</u> <u>51</u> <u>138</u> <u>51</u> <u>4,327</u>	Additions to non-current assets (other than financial	2,170	102	3	19	124	41	2,341
	tax assets)	4,138	67	20	51	138	51	4,327

#### As at December 31, 2016

	Innovation Platform		Commercial	Platform			
	Drug R&D	Prescription Drugs	Consumo	er Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				(in US\$'000)			
Total assets	53,774	134,681	67,161	10,701	212,543	76,120	342,437
Property, plant and equipment	9,686	145	34	40	219	49	9,954
Leasehold land	1,220	_	_	_	_	_	1,220
Goodwill	_	2,730	407	_	3,137	_	3,137
Other intangible asset	_	469	_	_	469	_	469
Investments in equity investees	17,031	77,939	63,536		141,475		158,506

	Innovation Platform		Commercial	Platform			
	Drug R&D	Prescription Drugs	Consume	er Health			
	PRC	PRC	PRC	Hong Kong	Subtotal	Unallocated	Total
				in US\$'000	)		
Revenue from external customers	52,016	105,478	3,028	17,681	126,187	_	178,203
Adjusted (LBIT)/EBIT	(119)	676	(169)	1,211	1,718	(11,186)	(9,587)
Interest income	79	114	29	1	144	228	451
Equity in earnings of equity investees, net of tax	(3,770)	15,653	10,689	_	26,342	_	22,572
Operating (loss)/profit	(3,810)	16,443	10,549	1,212	28,204	(10,958)	13,436
Interest expense		_	· —	85	85	1,319	1,404
Income tax expense	_	239	_	148	387	1,218	1,605
Net (loss)/income attributable							

Year ended December 31, 2015

Revenue from external customers is after elimination of inter-segment sales. The amount eliminated attributable to sales within Consumer Health business from Hong Kong to the PRC was US\$2,536,000, US\$1,306,000 and US\$2,874,000 for the years ended December 31, 2017, 2016 and 2015 respectively. Sales between segments are carried out at mutually agreed terms.

15,934

94

88

8,640

5

581

5

4

25,155

110

97

(13,352)

9

7,993

2,015

3,324

There were no customers who accounted for over 10% of the Group's revenue for the years ended December 31, 2017 and 2016. There was one customer under the Innovation Platform which accounted for 23% of the Group's revenue for the year ended December 31, 2015.

Unallocated expenses mainly represent corporate expenses which include corporate employee benefit expenses and the relevant share-based compensation expenses. Unallocated assets mainly comprise cash and cash equivalents and short-term investments.

A reconciliation of Adjusted LBIT to net (loss)/income is as follows:

(3,810)

1,864

3,218

to ordinary shareholders of

Additions to non-current assets (other than financial instrument and deferred tax

Depreciation/amortization

the Company

assets)

	Year Ended December 31,			
	2017 2016		2015	
		(in US\$'000)		
Adjusted LBIT	(53,301)	(46,227)	(9,587)	
Interest income	1,220	502	451	
Equity in earnings of equity investees, net of tax	33,653	66,244	22,572	
Interest expense	(1,455)	(1,631)	(1,404)	
Income tax expense	(3,080)	(4,331)	(1,605)	
Net (loss)/income	(22,963)	14,557	10,427	

#### 26. Note to Consolidated Statements of Cash Flows

Reconciliation of net (loss)/income for the year to net cash used in operating activities:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Net (loss)/income	(22,963)	14,557	10,427
Adjustments to reconcile net (loss)/income to net cash used in			
operating activities			
Amortization of finance costs	147	92	62
Depreciation and amortization	2,578	2,341	2,015
Loss on retirement of property, plant and equipment	57	30	60
Provision for excess and obsolete inventories	(16)	163	4
Provision for doubtful accounts	242	(208)	1,408
Share-based compensation expense—share options	1,316	1,780	1,151
Share-based compensation expense—LTIP	3,423	1,661	308
Equity in earnings of equity investees, net of tax	(33,653)	(66,244)	(22,572)
Dividends received from equity investees	55,586	30,528	6,410
Unrealized currency translation (gain)/loss	(399)	633	198
Changes in income tax balances	(756)	1,667	1,093
Changes in working capital			
Accounts receivable—third parties	2,160	(7,258)	(12,030)
Accounts receivable—related parties	363	(2,354)	315
Other receivables, prepayments and deposits	(6,982)	(1,129)	(459)
Amounts due from related parties	220	1,157	(3,010)
Inventories	1,049	(3,430)	(5,154)
Long-term prepayment	123	361	(2,132)
Accounts payable	(11,173)	11,452	3,659
Other payables, accruals and advance receipts	5,194	7,554	4,660
Deferred revenue	(897)	(1,668)	(1,907)
Other deferred income	(275)	131	2,132
Amounts due to related parties	(4,287)	(1,385)	3,977
Total changes in working capital	(14,505)	3,431	(9,949)
Net cash used in operating activities	(8,943)	(9,569)	(9,385)

#### 27. Litigation

From time to time, the Group may become involved in litigation relating to claims arising from the ordinary course of business. The Group believes that there are currently no claims or actions pending against the Group, the ultimate disposition of which could have a material adverse effect on the Group's results of operations, financial position or cash flows. However, litigation is subject to inherent uncertainties and the Group's view of these matters may change in the future. When an unfavorable outcome occurs, there exists the possibility of a material adverse impact on the Group's financial position and results of operations for the periods in which the unfavorable outcome occurs, and potentially in future periods.

#### 28. Restricted Net Assets

Relevant PRC laws and regulations 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 PRC accounting standards and regulations. In addition, the Company's subsidiaries in the PRC are required to make

certain appropriations of net after-tax profits or increases in net assets to the statutory surplus fund prior to payment of any dividends. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in the PRC, up to the amount of net assets held in each subsidiary. As a result of these and other restrictions under PRC laws and regulations, the Company's subsidiaries in the PRC are restricted in their ability to transfer their net assets to the Group in terms of cash dividends, loans or advances, with restricted portions amounting to US\$7,277,000 and US\$6,847,000 as at December 31, 2017 and 2016 respectively, which excludes the Company's subsidiaries with a shareholders' deficit. Even though the Group currently does not require any such dividends, loans or advances from the PRC subsidiaries, for working capital and other funding purposes, the Group may in the future require additional cash resources from the Company's subsidiaries in the PRC due to changes in business conditions, to fund future acquisitions and development, or merely to declare and pay dividends to make distributions to shareholders.

In addition, the Group has certain investments in equity investees in the PRC, where the Group's equity in undistributed earnings amounted to US\$85,400,000 and US\$116,953,000 as at December 31, 2017 and 2016 respectively.

#### 29. Subsequent Events

The Group evaluated subsequent events through March 12, 2018, which is the date when the consolidated financial statements were issued.

# SHANGHAI HUTCHISON PHARMACEUTICALS LIMITED

#### **Report of Independent Auditors**

#### To the Board of Directors and Shareholders of Shanghai Hutchison Pharmaceuticals Limited

We have audited the accompanying consolidated financial statements of Shanghai Hutchison Pharmaceuticals Limited and its subsidiaries, which comprise the consolidated statements of financial position as of December 31, 2017 and 2016, and the related consolidated income statements, consolidated statements of comprehensive income, of changes in equity and of cash flows for each of the three years in the period ended December 31, 2017.

#### Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditors' Responsibility

Our responsibility is to express an opinion on the consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the Company's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Shanghai Hutchison Pharmaceuticals Limited and its subsidiaries as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

/s/ PricewaterhouseCoopers Zhong Tian LLP Shanghai, the People's Republic of China March 9, 2018

# Shanghai Hutchison Pharmaceuticals Limited Consolidated Income Statements (in US\$'000)

		Year Ended December 31,		
	Note	2017	2016	2015
Revenue	5	244,557	222,368	181,140
Cost of sales		(68,592)	(64,237)	(53,532)
Gross profit		175,965	158,131	127,608
Selling expenses		(104,504)	(92,487)	(78,429)
Administrative expenses		(13,257)	(13,278)	(12,317)
Other net operating income	6	8,293	7,242	539
Gain on disposal of assets held for sale	7		88,536	
Profit before taxation	8	66,497	148,144	37,401
Taxation charge	9	(10,874)	(27,645)	(6,094)
Profit for the year		55,623	120,499	31,307

# Shanghai Hutchison Pharmaceuticals Limited Consolidated Statements of Comprehensive Income (in US\$'000)

	Year I	Year Ended December 31,			
	2017	2016	2015		
Profit for the year	55,623	120,499	31,307		
Other comprehensive income/(loss) that has been or may be reclassified subsequently to profit or loss:					
Exchange translation differences	8,273	(8,571)	(3,540)		
Total comprehensive income	63,896	111,928	27,767		

# Shanghai Hutchison Pharmaceuticals Limited Consolidated Statements of Financial Position (in US\$'000)

		Decembe	r 31,
	Note	2017	2016
Assets			
Current assets			
Cash and cash equivalents	11	43,527	20,292
Bank deposits maturing over three months	11	_	40,205
Trade and bills receivables	12	22,445	23,718
Other receivables, prepayments and deposits	13	2,456	11,262
Inventories	14	61,107	47,844
Total current assets		129,535	143,321
Property, plant and equipment	15	90,734	88,390
Leasehold land		7,528	7,244
Other intangible asset		1,621	1,741
Deferred tax assets	16	3,594	3,310
Total assets		233,012	244,006
Liabilities and shareholders' equity	•		
Current liabilities			
Trade payables	17	11,773	7,979
Other payables, accruals and advance receipts	18	74,551	65,249
Current tax liabilities	19	5,341	13,718
Total current liabilities		91,665	86,946
Deferred income		8,616	6,926
Total liabilities		100,281	93,872
Shareholders' equity			
Share capital		33,382	33,382
Reserves		99,349	116,752
Total shareholder's equity		132,731	150,134
Total liabilities and shareholders' equity		233,012	244,006
	:		

# Shanghai Hutchison Pharmaceuticals Limited Consolidated Statements of Changes in Equity (in US\$'000)

	Share capital	Exchange reserve	General reserves	Retained earnings	Total equity
As at January 1, 2015	33,382	5,781	925	31,818	71,906
Profit for the year	_	_	_	31,307	31,307
Other comprehensive loss					
Exchange translation differences		(3,540)			(3,540)
Total comprehensive (loss)/income		(3,540)		31,307	27,767
Dividends declared to shareholders				(6,410)	(6,410)
As at December 31, 2015	33,382	2,241	925	56,715	93,263
Profit for the year	_	_	_	120,499	120,499
Other comprehensive loss					
Exchange translation differences		(8,571)			(8,571)
Total comprehensive (loss)/income		(8,571)		120,499	111,928
Transfer between reserves		_	30	(30)	_
Dividends declared to shareholders				(55,057)	(55,057)
As at December 31, 2016	33,382	(6,330)	955	122,127	150,134
Profit for the year	_	_	_	55,623	55,623
Other comprehensive income					
Exchange translation differences		8,273			8,273
Total comprehensive income		8,273		55,623	63,896
Transfer between reserves	_	_	15	(15)	_
Dividends declared to shareholders				(81,299)	(81,299)
As at December 31, 2017	33,382	1,943	970	96,436	132,731

## Shanghai Hutchison Pharmaceuticals Limited Consolidated Statements of Cash Flows (in US\$'000)

		Year E	r 31,	
	Note	2017	2016	2015
Operating activities				
Net cash generated from operations	20	78,503	64,310	51,007
Interest received		844	467	300
Income tax paid	19	(19,887)	(15,595)	(6,199)
Net cash generated from operating activities		59,460	49,182	45,108
Investing activities				
Purchase of property, plant and equipment	15	(7,744)	(11,171)	(44,899)
Deposits into bank deposits maturing over three months		(19,076)	(57,001)	(3,087)
Proceeds from bank deposits maturing over three months		59,281	20,563	1,619
Proceeds from disposal of property, plant and equipment		_	4	1
Proceeds from disposal of assets held for sale, net of costs	7	9,776	58,839	31,146
Capitalized interest expense paid for property, plant and				
equipment	15		(768)	(1,934)
Government grants received relating to property, plant and		4 5 60		2046
equipment		1,569	166	2,816
Net cash generated from/(used in) investing activities		43,806	10,632	(14,338)
Financing activities				
Dividends paid to shareholders		(81,299)	(55,057)	(6,410)
Proceeds from bank borrowings		_	_	16,764
Repayment of bank borrowings			(25,577)	(13,176)
Net cash used in financing activities		(81,299)	(80,634)	(2,822)
Net increase/(decrease) in cash and cash equivalents		21,967	(20,820)	27,948
Effect of exchange rate changes on cash and cash equivalents		1,268	(2,029)	(1,382)
		23,235	(22,849)	26,566
Cash and cash equivalents			, i	
Cash and cash equivalents at beginning of year		20,292	43,141	16,575
Cash and cash equivalents at end of year		43,527	20,292	43,141

#### Shanghai Hutchison Pharmaceuticals Limited Notes to the Consolidated Financial Statements

#### 1. General Information

Shanghai Hutchison Pharmaceuticals Limited (the "Company") and its subsidiaries (together the "Group") are principally engaged in manufacturing, selling and distribution of prescription drug products. The Group has manufacturing plants in the People's Republic of China (the "PRC") and sells mainly in the PRC.

The Company was incorporated in the PRC on April 30, 2001 as a Chinese-Foreign Equity joint venture and the approved operation period is 50 years. The Company is jointly controlled by Shanghai Hutchison Chinese Medicine (HK) Investment Limited ("SHCM(HK)IL") and Shanghai Traditional Chinese Medicine Co., Ltd ("SHTCML").

These consolidated financial statements are presented in United States dollars ("US\$"), unless otherwise stated and have been approved for issue by the Company's Board of Directors on March 9, 2018.

#### 2. Summary of Significant Accounting Policies

The consolidated financial statements of the Company have been prepared in accordance with International Financial Reporting Standards ("IFRS") and interpretations issued by the IFRS Interpretations Committee applicable to companies reporting under IFRS. The consolidated financial statements comply with IFRS as issued by the International Accounting Standards Board ("IASB"). These consolidated financial statements have been prepared under the historical cost convention.

During the year, the Group has adopted all of the new standards, amendments and interpretations issued by the IASB that are relevant to the Group's operations and mandatory for annual periods beginning January 1, 2017. The adoption of these new standards, amendments and interpretations did not have any material effects on the Group's results of operations or financial position.

The following standards, amendments and interpretations were in issue but not yet effective for financial year ended December 31, 2017 and have not been early adopted by the Group:

IAS 28 (Amendments) <sup>(1)</sup>	Investments in Associates and Joint Ventures
IAS 40 (Amendments) <sup>(1)</sup>	Transfers of Investment Property
IFRS 2 (Amendments) <sup>(1)</sup>	Classification and Measurement of Share-based
	Payment Transactions
IFRS 9 <sup>(1)</sup>	Financial Instruments
IFRS 10 and IAS 28 (Amendments) <sup>(3)</sup>	Sale or Contribution of Assets between an
	Investor and its Associate or Joint Venture
IFRS 15 <sup>(1)</sup>	Revenue from Contracts with Customers
IFRS 15 (Amendments) <sup>(1)</sup>	Revenue from Contracts with Customers
IFRS 16 <sup>(2)</sup>	Leases
IFRIC 22 <sup>(1)</sup>	Foreign Currency Transactions and Advance
	Consideration
IFRIC 23 <sup>(2)</sup>	Uncertainty over Income Tax Treatments
Annual improvement 2014-2016 <sup>(1)</sup>	Improvements to IFRSs
Annual improvement 2015-2017 <sup>(2)</sup>	Improvements to IFRSs

- (1) Effective for the Group for annual periods beginning on or after January 1, 2018.
- (2) Effective for the Group for annual periods beginning on or after January 1, 2019.

#### (3) No mandatory effective date determined yet, but available for adoption.

The adoption of standards, amendments and interpretations listed above in future periods is not expected to have any material effects on the Group's results of operations or financial position, except for the adoption of IFRS 16 for which management is still assessing the impact.

Based on its evaluation of IFRS 15 and its Amendments, the Group expects there will not be a material impact to the timing of revenue recognition. The Group expects the timing of recognition will be at the point when the goods have been transferred to the customer and the customer obtains control of the goods as evidenced by delivery of the product, transfer of title and when no further obligations to the customer remain. The Group will adopt the new standard using the modified retrospective method in the year commencing January 1, 2018.

#### (a) Basis of Consolidation

The consolidated financial statements of the Group include the financial statements of the Company and its subsidiaries.

The accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Intercompany transactions, balances and unrealized gains on transactions between group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

#### (b) Subsidiaries

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights, to variable return from its involvement with the entity and has the ability to affect those returns through its power over the entity. In the consolidated financial statements, subsidiaries are accounted for as described in Note 2(a) above.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

#### (c) Foreign Currency Translation

Items included in the financial statements of each of the Group's companies are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The functional currency of the Company and its subsidiaries is Renminbi ("RMB") whereas the consolidated financial statements are presented in US\$, which is the Company's presentation currency.

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign currency gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in the income statement.

The financial statements of the Company and its subsidiaries are translated into the Company's presentation currency using the year end rates of exchange for the statements of financial position items and the average rates of exchange for the year for the income statement items. Exchange translation differences are recognized directly in other comprehensive income/(loss).

#### (d) Property, Plant and Equipment

Property, plant and equipment other than construction in progress are stated at historical cost less accumulated depreciation and any accumulated impairment losses. Historical cost includes the purchase

price of the asset and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate asset costs less accumulated impairment losses over their estimated useful lives. The principal estimated useful lives are as follows:

Buildings	30 years
Leasehold improvements	Over the unexpired period of the lease
1	or 5 years, whichever is shorter
Plant and equipment	10 years
Furniture and fixtures, other equipment	•
and motor vehicles	5 years

The assets' useful lives are reviewed and adjusted, if appropriate, at the end of each reporting period. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing net sales proceeds with the carrying amount of the relevant assets and are recognized in the income statement.

#### (e) Construction in Progress

Construction in progress represents buildings, plant and machinery under construction and pending installation and is stated at cost less accumulated impairment losses, if any. Cost includes the costs of construction of buildings and the costs of plant and machinery. No provision for depreciation is made on construction-in-progress until such time as the relevant assets are completed and ready for intended use. When the assets concerned are brought into use, the costs are transferred to property, plant and equipment and depreciated in accordance with the policy as stated in Note 2(d).

#### (f) Leasehold Land

Leasehold land is stated at cost less accumulated amortization and accumulated impairment losses, if any. Cost mainly represents consideration paid for the rights to use the land on which various plants and buildings are situated for a period of 50 years from the date the respective right was granted. Amortization of leasehold land is calculated on a straight-line basis over the period of the land use rights.

#### (g) Other Intangible Asset

The Group's other intangible asset represents promotion and marketing rights. Other intangible asset has a definite useful life and is carried at historical cost less accumulated amortization and accumulated impairment losses, if any. Amortization is calculated using the straight-line method to allocate its cost over its estimated useful life of ten years.

#### (h) Research and Development

Research expenditure is recognized as an expense as incurred. Costs incurred on development projects (relating to the design and testing of new or improved products) are recognized as intangible assets when it is probable that the project will generate future economic benefits by considering its commercial and technological feasibility, and costs can be measured reliably. Other development expenditures are recognized as an expense as incurred. Development costs previously recognized as an

expense are not recognized as an asset in a subsequent period. Development costs with a finite useful life that have been capitalized, if any, are amortized on a straight-line basis over the period of expected benefit not exceeding five years. The capitalized development costs are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset exceeds its recoverable amount.

Where the research phase and the development phase of an internal project cannot be clearly distinguished, all expenditure incurred on the project is charged to the income statement.

#### (i) Impairment of Non-Financial Assets

Assets that have an indefinite useful life such as goodwill or intangible assets not ready to use are not subject to amortization and are tested for impairment annually. Assets are reviewed for impairment to determine whether there is any indication that the carrying value of these assets may not be recoverable and have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss, if any. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. Such impairment loss is recognized in the income statement.

#### (j) Non-Current Assets Classified As Held For Sale

Non-current assets are classified as held for sale when their carrying amount is to be recovered principally through a sale transaction and a sale is considered highly probable. The non-current assets are stated at the lower of carrying amount and fair value less costs to sell. Property, plant and equipment and leasehold land classified as held for sale are not depreciated and amortized.

#### (k) Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the weighted average cost method. The cost of finished goods comprises raw materials, direct labor, other direct costs and related production overheads (based on normal operating capacity). Net realizable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses.

#### (1) Trade and Other Receivables

Trade and other receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less provision for impairment. A provision for impairment of trade and other receivables is established when there is objective evidence that the asset is impaired. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the effective interest rate. The amount of the provision is recognized in the income statement.

#### (m) Cash and Cash Equivalents

In the consolidated statements of cash flows, cash and cash equivalents include cash on hand, bank deposits and other short-term highly liquid investments with original maturities of three months or less.

#### (n) Borrowings

Borrowings are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method.

#### (o) Financial Liabilities and Equity Instruments

Financial liabilities and equity instruments issued by the Group are classified according to the substance of the contractual arrangements entered into and the definitions of a financial liability and an equity instrument. Financial liabilities (including trade and other payables) are initially measured at fair value, and are subsequently measured at amortized cost, using the effective interest method. An equity instrument is any contract that does not meet the definition of a financial liability and evidences a residual interest in the assets of the Group after deducting all of its liabilities.

Ordinary shares are classified as equity. Incremental costs, net of tax, directly attributable to the issue of new shares are shown in equity as a deduction from the proceeds.

#### (p) Current and Deferred Income Tax

#### (i) Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the country where the Group operates and generates taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

#### (ii) Deferred income tax

#### Inside basis differences

Deferred income tax is recognized, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill and the deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

#### Outside basis differences

Deferred income tax liabilities are provided on taxable temporary differences arising from investments in subsidiaries, except for deferred income tax liabilities where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred income tax assets are recognized on deductible temporary differences arising from investments in subsidiaries, only to the extent that it is probable the temporary difference will reverse in the future and there is sufficient taxable profit available against which the temporary difference can be utilized.

#### (q) Employee Benefits

The employees of the Group participate in defined contribution retirement benefit plans managed by the relevant municipal and provincial governments in the PRC. The assets of these plans are held separately from those of the Group. The Group is required to make monthly contributions to the plans calculated as a percentage of the employees' salaries. The municipal and provincial governments undertake to assume the retirement benefit obligations to all existing and future retired employees under the plans described above. Other than the monthly contributions, the Group has no further obligations for the payment of the retirement and other post-retirement benefits of its employees.

#### (r) Provisions

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events; it is probable that an outflow of resources will be required to settle the obligation; and the amount has been reliably estimated. Provisions are not recognized for future operating losses.

#### (s) Operating Leases

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the income statement on a straight-line basis over the period of the leases.

#### (t) Borrowing Costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, which are assets that necessarily take a substantial period of time to get ready for their intended use or sale, are added to the cost of those assets, until such time as the assets are substantially ready for their intended use or sale. All other borrowing costs are recognized in the income statement in the period in which they are incurred.

#### (u) Government Incentives

Incentives from government are recognized at their fair values where there is a reasonable assurance that the incentives will be received and all attached conditions will be complied with.

Government incentives relating to costs are deferred and recognized in the income statement over the period necessary to match them with the costs that they are intended to compensate.

Government grants relating to property, plant and equipment are included in non-current liabilities as deferred income and credited to the income statement on a straight-line basis over the expected lives of the related assets.

#### (v) Revenue and Income Recognition

Revenue comprises the fair value of the consideration received and receivable for the sales of goods in the ordinary course of the Group's activities. The Group recognizes revenue when the amount of revenue can be reliably measured; when it is probable that future economic benefits will flow to the entity; and when specific criteria have been met for each of the Group's activities, as described below.

Revenue is shown net of value-added tax, returns, volume rebates and discounts after eliminated sales within the Group. Revenue and income are recognized as follows:

#### (i) Sales of goods

Sales of goods are recognized when a group entity has delivered products to the customer, the customer has accepted the products and collectability of the related receivables is reasonably assured.

#### (ii) Sales rebates

Certain sales rebates are provided to customers when their business performance for an agreed period within the year and the whole year meets certain criteria. Sales rebates are recognized in profit or loss based on management's estimation at each year end.

#### (iii) Other service income

Other service income is recognized when services are rendered.

#### (iv) Interest income

Interest income is recognized on a time-proportion basis using the effective interest method.

#### (w) Segment Reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision makers. The Board of Directors, which is responsible for allocating resources and assessing performance of the operating segments, has been identified as the steering committee that makes strategic decisions.

#### (x) General Reserves

In accordance with the laws applicable to Foreign Investment Enterprises established in the PRC, the Company makes appropriations to certain non-distributable reserve funds including the general reserve fund, the enterprise expansion fund and the staff bonus and welfare fund. The amount of appropriations to these funds are made at the discretion of the Company's Board of Directors.

#### 3. Financial Risk Management

#### (a) Financial risk factors

The Group's activities expose it to a variety of financial risks, including credit risk, cash flow interest rate risk and liquidity risk. The Group does not use any derivative financial instruments for speculative purposes.

#### (i) Credit risk

The carrying amounts of cash at bank, bank deposits, trade receivables (including bills receivables) and other receivables included in the consolidated statements of financial position represent the Group's maximum exposure to credit risk of the counterparty in relation to its financial assets.

Substantially all of the Group's cash at banks is deposited in major financial institutions, which management believes are of high credit quality. The Group has a practice to limit the amount of credit exposure to any financial institution.

Bills receivables are mostly settled by state-owned banks or other reputable banks and therefore the management considers that they will not expose the Group to any significant credit risk.

The Group has no significant concentrations of credit risk. The Group has policies in place to ensure that the sales of products are made to customers with appropriate credit history and the Group performs periodic credit evaluations of its customers.

Management periodically assesses the recoverability of trade receivables and other receivables. The Group's historical experience collecting receivables falls within the recorded allowances.

#### (ii) Cash flow interest rate risk

The Group has no significant interest-bearing assets except for bank deposits and cash at bank, details of which have been disclosed in Note 11. The Group's exposure to interest rate risk would mainly be to bank borrowings which bear interest at fixed rates.

#### (iii) Liquidity risk

Prudent liquidity management implies maintaining sufficient cash and cash equivalents and the availability of funding when necessary. The Group's policy is to regularly monitor current and expected liquidity requirements to ensure that it maintains sufficient cash balances and adequate credit facilities to meet its liquidity requirements in the short and long term.

As at December 31, 2017 and 2016, the Group's current financial liabilities were mainly due for settlement within twelve months and the Group expects to meet all liquidity requirements.

#### (b) Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group regularly reviews and manages its capital structure to ensure an optimal balance between higher shareholders' return that might be possible with higher levels of borrowings and the advantages and security afforded by a sound capital position, and makes adjustments to the capital structure in light of changes in economic conditions.

The Group monitors capital on the basis of the liabilities to assets ratio. This ratio is calculated as total liabilities divided by total assets as shown on the consolidated statements of financial position.

Currently, it is the Group's strategy to maintain a reasonable liabilities to assets ratio. The liabilities to assets ratio as at December 31, 2017 and 2016 was as follows:

	Decem	ber 31,	
	2017	2016	
	(in US	<b>5</b> \$'000)	
Total liabilities	100,281	93,872	
Total assets	233,012	244,006	
Liabilities to assets ratio	43.0%	38.5%	

#### (c) Fair value estimation

The Group does not have any financial assets or liabilities which are carried at fair value. The carrying amounts of the Group's current financial assets, including cash and bank balances, trade and bills receivables, and other receivables and current financial liabilities, including trade payables and other payables and accruals approximate their fair values due to their short-term maturities. The carrying amounts of the Group's financial instruments carried at cost or amortized cost are not materially different from their fair values.

The face values less any estimated credit adjustments for financial assets and liabilities with a maturity of less than one year are assumed to approximate their fair values. The fair value of financial liabilities for disclosure purposes is estimated by discounting the future contractual cash flows at the current market interest rate that is available to the Group for similar financial instruments.

#### 4. Critical Accounting Estimates and Judgements

Note 2 includes a summary of the significant accounting policies used in the preparation of the financial statements. The preparation of financial statements often requires the use of judgements to select specific accounting methods and policies from several acceptable alternatives. Furthermore, significant estimates and assumptions concerning the future may be required in selecting and applying those methods and policies in the financial statements. The Group bases its estimates and judgements on historical

experience and various other assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates and judgements under different assumptions or conditions.

The following is a review of the more significant assumptions and estimates, as well as the accounting policies and methods used in the preparation of the consolidated financial statements.

#### (a) Sales rebates

Certain sales rebates are provided to customers when their business performance for an agreed period within the year and the whole year meets certain criteria as stipulated in the contracts. The estimate of sales rebates during the year is based on estimated sales transactions for the entire period stipulated and is subject to change based on actual performance and collection status.

#### (b) Useful lives of property, plant and equipment

The Group has made substantial investments in property, plant and equipment. Changes in technology or changes in the intended use of these assets may cause the estimated period of use or value of these assets to change.

#### (c) Impairment of receivables

The Group makes provision for impairment of receivables based on an assessment of the recoverability of the receivables. This assessment is based on the credit history of the relevant counterparty and the current market condition. Provisions are made where events or changes in circumstances indicate that the receivables may not be collectible. The identification of impairment in receivables requires the use of judgement and estimates. Where the expectation is different from the original estimate, such difference will impact the carrying amount of receivables and impairment is recognized in the period in which such estimate has been changed.

#### (d) Deferred income tax

Deferred tax is recognized using the liability method on temporary differences arising between the tax bases of assets and liabilities against which the deductible temporary differences and the carry forward of unused tax losses and tax credits can be utilized. Where the final outcomes are different from the estimations, such differences will impact the carrying amount of deferred tax in the period in which such determination is made.

#### (e) Disposal of assets classified as held for sale

On October 20, 2016, the Group completed the disposal of assets classified as held for sale, including leasehold land and property, plant and equipment, to the municipal government. 90% of the consideration had been collected as of December 31, 2016, and the remaining 10% was collected in February 2017. The gain of US\$88.5 million representing the consideration less the assets classified as held for sale was recognized in full on the disposal date. The Group determined that the whole transaction had been completed on October 20, 2016 since the risk and rewards of ownership of the land had been passed to the municipal government, no additional costs were expected to be incurred and there was no receivable recoverability risk.

#### 5. Revenue and Segment Information

Management has reviewed the Group's internal reporting in order to assess performance and allocate resources, and has determined that the Group has two reportable operating segments as follows:

-Manufacturing business-manufacture and distribution of drug products

—Distribution business—provision of sales, distribution and marketing services to pharmaceutical manufacturers

The operating segments are strategic business units that offer different products and services. They are managed separately because each business requires different technology and marketing approaches. The performance of each of the reportable segments is assessed based on a measure of earnings or losses before interest income, finance costs and taxation charge ("Adjusted EBIT/(LBIT)"). The aggregate amount of operating profit/(loss) for the two operating segments is the same as profit before taxation in the consolidated income statements for each of the years presented.

The segment information for the reportable segments for the year is as follows:

	Year E	anded December 31, 2	2017
	Manufacturing business	Distribution business	
	PRC	PRC	Total
		(in US\$'000)	
Revenue from external customers	226,429	18,128	244,557
Adjusted EBIT/(LBIT)	65,920	(180)	65,740
Interest income	603	154	757
Operating profit/(loss)	66,523	(26)	66,497
Depreciation/amortization	6,917	25	6,942
Additions to non-current assets (other than financial instrument and deferred tax assets)	3,469	3	3,472
	As	at December 31, 201	7
Total garment agests	221 007	(in US\$'000)	222.012
Total segment assets	221,997	11,015	233,012
	Year E	anded December 31, 2	2016
	Manufacturing business	Distribution business	
	PRC	PRC	Total
		(in US\$'000)	
Revenue from external customers	205,809	16,559	222,368
Adjusted EBIT/(LBIT)	169,312	(21,733)	147,579
Interest income	562	3	565
Operating profit/(loss)	169,874	(21,730)	148,144
Depreciation/amortization	3,503	23	3,526
Impairment of property, plant and equipment	1,174	_	1,174
Additions to non-current assets (other than financial instrument and			, .
deferred tax assets)	11,919	20	11,939
	As	at December 31, 201	6
		(in US\$'000)	-
Total segment assets	239,843	4,163	244,006

	Year Ended December 31, 2015		
	Manufacturing business	Distribution business	
	PRC	PRC	Total
		(in US\$'000)	
Revenue from external customers	174,821	6,319	181,140
Adjusted EBIT/(LBIT)	39,387	(2,292)	37,095
Interest income	301	5	306
Operating profit/(loss)	39,688	(2,287)	37,401
Depreciation/amortization	2,742	23	2,765
Additions to non-current assets (other than			
financial instrument and deferred tax assets)	49,231	6	49,237

#### 6. Other Net Operating Income

	Year E	Year Ended December 31,			
	2017	2016	2015		
		(in US\$'000)			
Interest income	757	565	306		
Net foreign exchange gain/(losses)	45	(51)	(25)		
Other government subsidy (Note 18)	6,388	6,560	_		
Other operating income	1,103	168	258		
	8,293	7,242	539		

#### 7. Gain on disposal of Assets Held for Sale

The Company's prior manufacturing facilities and factory site ("the Site") was located in Putuo District, Shanghai, an area of Shanghai 12 kilometers from the city centre. The area was re-zoned in 2014 from industrial usage into a new science and technology, commercial and residential development area called Smart City.

On December 9, 2015, the Company entered into an agreement ("the Agreement") with the relevant Shanghai government authorities for the surrender of its then remaining 36 years land-use right in respect of the Site. Under the Agreement, the Company received cash compensation in three installments. As at December 31, 2015, the Company received the first installment of approximately US\$ 31.1 million of the compensation (which was equivalent to approximately US\$29.9 million in October 2016 based on the prevailing exchange rate at that time).

In October 2016, the Company completed the surrender of the Site and received the second installment of US\$59.7 million. Upon the disposal of the non-current assets classified as held for sales, the Company derecognized the carrying values of the non-current assets classified as held for sales amounted to approximately US\$10.1 million, and recognized a gain of US\$88.5 million after deducting the costs of US\$0.9 million. The remaining US\$9.7 million final installment (which was equivalent to US\$9.9 million in October 2016 based on the prevailing exchange rate at that time) was recorded as a current asset as at December 31, 2016. In February 2017, the Company received the final installment of the land compensation (which was equivalent to US\$9.8 million based on the prevailing exchange rate at that time).

### 8. Profit before taxation

Year 1	Year Ended December 31,		
2017	2016	2015	
	(in US\$'000)		
66,497	148,144	37,401	
	2017	2017 2016 (in US\$'000)	

Profit before taxation is stated after charging/(crediting) the following:

	Year I	Ended Decembe	r 31,
	2017	2016	2015
		(in US\$'000)	
Cost of inventories recognized as expense	45,683	47,047	32,378
Depreciation of property, plant and equipment	6,556	3,135	2,277
Impairment of property, plant and equipment	_	1,174	_
Loss on disposal of property, plant and equipment	2	179	34
Amortization of leasehold land	164	166	271
Amortization of other intangible asset	222	225	217
Operating lease rentals in respect of land and			
buildings	856	737	670
Reversal of provision for trade receivables	_	(81)	_
Provision for excess and obsolete inventories	994	1,236	1,569
Research and development expense	3,414	1,753	1,442
Auditor's remuneration	163	138	71
Employee benefit expenses (Note 10)	70,401	61,092	49,398

# 9. Taxation Charge

	Year E	Year Ended December 31,		
	2017	2016	2015	
		(in US\$'000)		
Current tax	10,949	26,709	7,928	
Deferred income tax (Note 16)	(75)	936	(1,834)	
Taxation charge	10,874	27,645	6,094	

The taxation charge on the Group's profit before taxation differs from the theoretical amount that would arise using the Group's weighted average tax rate as follows:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Profit before taxation	66,497	148,144	37,401
Tax calculated at the statutory tax rates of			
respective companies	16,624	37,036	9,351
Tax effects of:			
Expenses not deductible for tax purposes	3,361	8,124	389
Temporary differences for which no deferred			
tax assets were recognized	555	_	_
Tax concession (note)	(8,497)	(18,203)	(4,101)
(Over)/under provision in prior years	(5)	237	(98)
Tax benefits from change in tax law	(1,538)	_	_
Rate change on deferred tax assets	113	_	_
Tax losses for which no deferred tax assets			
were recognized	261	451	553
Taxation charge	10,874	27,645	6,094

Note: The Company has been granted the High and New Technology Enterprise status. Accordingly, the Company is subjected to a preferential income tax rate of 15.0% in 2017 and up to 2019 (2016: 15.0%; 2015: 15.0%). Certain research and development expenses are also eligible for super-deduction such that 150% of qualified expenses incurred are deductible for tax purposes.

The weighted average tax rate calculated at the statutory tax rates of respective companies for the year was 25.0% (2016: 25.0%; 2015: 25.0%). The effective tax rate for the year was 16.4% (2016: 18.7%; 2015: 16.3%).

#### 10. Employee Benefit Expenses

	Year Ended December 31,			
	2017	2016	2015	
		(in US\$'000)		
Wages, salaries and bonuses	54,444	48,350	32,776	
Pension costs—defined contribution plans	6,635	4,929	3,837	
Staff welfare	9,322	7,813	12,785	
	_70,401	61,092	49,398	

Employee benefit expenses of approximately US\$14,276,000 (2016: US\$13,548,000; 2015: US\$19,585,000) are included in cost of sales.

#### 11. Cash and bank balances

	Decem	ber 31,
	2017	2016
	(in US	\$'000)
Cash at bank and on hand	43,527	20,292
Bank deposits maturing over three months (note)		40,205
Cash and bank balances	43,527	60,497

Note: The weighted average effective interest rate on 2016 bank deposits, with maturity ranging from 37 days to 181 days was 2.1% per annum. Cash at bank earns interest at floating rates based on daily bank deposit rates.

The cash and bank balances denominated in RMB were deposited with banks in the PRC. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

#### 12. Trade and Bills Receivables

	Decem	ber 31,
	2017	2016
	(in US	<b>\$</b> '000)
Trade receivables—third parties	11,614	10,657
Trade receivables—related parties (Note 22(b))	6,966	7,010
Bills receivables	3,865	6,051
	22,445	23,718

All the trade and bills receivables are denominated in RMB and are due within one year from the end of the reporting period.

The carrying value of trade and bills receivables approximates their fair values.

Movements on the provision for trade receivables are as follows:

	2017	2016	2015
		(in US\$'000)	
As at January 1	_	131	137
Reversal of provision for trade receivables	_	(81)	_
Decreased due to collection or write-off	_	(45)	_
Exchange difference		(5)	(6)
As at December 31		_	131

There are no impaired receivables as at December 31, 2017 and December 31, 2016.

# 13. Other Receivables, Prepayments and Deposits

	Decemb	per 31,
	2017	2016
	(in US	\$'000)
Prepayments to suppliers	358	112
Interest receivables		87
Deposits	846	7
Receivable from disposal of asset held for sale (Note 7)		9,690
Others	1,252	1,366
	2,456	11,262

#### 14. Inventories

	Decer	nber 31,
	2017	2016
	(in U	S\$'000)
Raw materials	37,851	29,010
Work in progress	12,656	10,161
Finished goods	_10,600	8,673
	61,107	47,844

Movements on the provision for excess and obsolete inventories are as follows:

	2017	2016 (in US\$'000)	2015
As at January 1	1,362	606	343
Provision for excess and obsolete inventories	994	1,236	1,569
Write-off	(522)	(406)	(1,309)
Exchange differences	88	(74)	3
As at December 31	1,922	1,362	606

# 15. Property, plant and equipment

	Buildings situated in the PRC	Leasehold improvements	Plant and equipment (in US	Furniture and fixtures, other equipment and motor vehicles \$'000)	Construction in progress	Total
Cost						
As at January 1, 2017	67,221	315	20,003	6,213	2,606	96,358
Additions	26	162	541	1,133	1,610	3,472
Disposals			(8)	(174)		(182)
Transfers	603	_	1,316	(15)	(1,904)	
Exchange differences	4,220	24	1,306	417	103	6,070
As at December 31, 2017	72,070	501	23,158	7,574	2,415	105,718
Accumulated depreciation and impairment						
As at January 1, 2017	1,120	134	2,613	2,927	1,174	7,968
Depreciation	3,468	62	2,038	988	_	6,556
Disposals	_	_	(6)	(174)	_	(180)
Exchange differences	175	10_	225	208	22	640
As at December 31, 2017	4,763	206	4,870	3,949	1,196	14,984
Net book value						
As at December 31, 2017	67,307	295	18,288	3,625	1,219	90,734

	Buildings situated in the PRC	Leasehold improvements	Plant and equipment (in US	Furniture and fixtures, other equipment and motor vehicles \$'000)	Construction in progress	Total
Cost						
As at January 1, 2016	_	318	1,403	3,925	82,837	88,483
Additions	_	15	349	801	10,774	11,939
Disposals		(177)	(293)	(234)	(120)	(824)
Transfers	70,222	179	16,553	1,817	(88,771)	_
Transfer from non-current assets classified as held for sale	_	1	2,794	266	_	3,061
Exchange differences	(3,001)	(21)	(803)	(362)	(2,114)	(6,301)
As at December 31, 2016	67,221	315	20,003	6,213	2,606	96,358
Accumulated depreciation and impairment						
As at January 1, 2016		279	898	2,515	_	3,692
Depreciation	1,168	45	1,251	671	_	3,135
Disposals	_	(177)	(246)	(218)	_	(641)
Impairment	_	<u> </u>			1,174	1,174
Transfer from non-current assets classified as held for						
sale		_	810	145		955
Exchange differences	(48)	(13)	(100)	(186)		(347)
As at December 31, 2016	1,120	134	2,613	2,927	1,174	7,968
Net book value						
As at December 31, 2016	66,101	181	17,390	3,286	1,432	88,390

	Buildings situated in the PRC	Leasehold improvements	Plant and equipment	and fixtures, other equipment and motor vehicles	Construction in progress	Total
			(in US	§'000)		
Cost						
As at January 1, 2015	23,065	2,156	13,660	4,266	39,346	82,493
Additions	_	5	71	470	46,287	46,833
Disposals		(41)	(47)	(163)		(251)
Transfers	_	_	_	34	(34)	_
Transfer to non-current assets classified as held for sale	(22.142)	(1.71()	(11.724)	(501)		(2(,004)
	(22,143)	(1,716)	(11,734)	(501)	(2.7(2)	(36,094)
Exchange differences	(922)	(86)	(547)	(181)	(2,762)	(4,498)
As at December 31, 2015		318	1,403	3,925	82,837	88,483
Accumulated depreciation and impairment						
As at January 1, 2015	16,385	1,368	9,199	2,587	_	29,539
Depreciation	851	244	610	572	_	2,277
Disposals	_	(37)	(34)	(145)	_	(216)
Transfer to non-current assets classified as held						
for sale	(16,559)	(1,237)	(8,493)	(384)	_	(26,673)
Exchange differences	(677)	(59)	(384)	(115)		(1,235)
As at December 31, 2015		279	898	2,515		3,692
Net book value						
As at December 31, 2015		39	505	1,410	82,837	84,791

Furniture

During the year ended December 31, 2017, finance cost from bank borrowings of nil (2016: US\$639,000; 2015: US\$2,029,000) was capitalized.

Construction in progress in 2015 and 2016 mainly related to the construction of a new factory in Fengpu District, Shanghai. In September 2016, the new factory was put into operation.

#### 16. Deferred Tax Assets

The movements in deferred tax assets are as follows:

	2017	2016	2015
		(in US\$'000)	
As at January 1	3,310	4,509	2,788
Credited/(debited) to the consolidated income statements			
—accrued expenses, provisions and depreciation			
allowances	75	(936)	1,834
Exchange differences	209	(263)	(113)
As at December 31	3,594	3,310	4,509

The Group's deferred tax assets are mainly temporary differences including accrued expenses, provisions and deferred income. The potential deferred tax assets in respect of tax losses which have not

been recognized in the consolidated financial statements were approximately US\$1,323,000 (2016: US\$944,000).

These unrecognized tax losses can be carried forward against future taxable income and will expire in the following years:

	Decem	ber 31,
	2017	2016
	(in Us	S\$' <mark>000</mark> )
2019	16	15
2020	2,134	2,008
2021	2,097	1,751
2022	1,045	
	5,292	3,774

# 17. Trade Payables

	Decem	December 31,		
	2017	2016		
	(in US	<b>\$</b> '000)		
Trade payables—third parties	8,774	6,323		
Trade payables—related parties (Note 22(b))	2,999	1,656		
	11,773	7,979		

All the trade payables are denominated in RMB and due within one year from the end of the reporting period. The carrying value of trade payables approximates their fair values due to their short-term maturities.

## 18. Other Payables, Accruals and Advance Receipts

	December 31,	
	2017	2016
	(in US	\$'000)
Other payables and accruals		
Accrued salaries and benefits	15,484	13,932
Accrued selling and marketing expenses	35,914	31,085
Value-added tax and tax surcharge payables	13,544	1,706
Others	7,450	12,437
	72,392	59,160
Advance receipts		
Payments in advance from customers	2,159	274
Payments in advance for other government subsidy (note)		5,815
	2,159	6,089
	74,551	65,249

Note: As at December 31, 2016, the Company had received and deferred approximately US\$5.8 million from a government subsidy relating to a research and development project. In May 2017, the Company met the criteria of the subsidy and recognized US\$5.9 million in other operating income, with difference due to exchange difference.

# 19. Current Tax Liabilities

	2017	2016	2015
		(in US\$'000)	
As at January 1	13,718	3,275	1,608
Current tax	10,949	26,709	7,928
Tax paid	(19,887)	(15,595)	(6,199)
Exchange difference	561	(671)	(62)
As at December 31	5,341	13,718	3,275

# 20. Notes to the Consolidated Statements of Cash Flows

# (a) Reconciliation of profit for the year to net cash generated from operations:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Profit for the year	55,623	120,499	31,307
Adjustments to reconcile profit for the year to net cash generated from operations			
Taxation charge	10,874	27,645	6,094
Interest income	(757)	(565)	(306)
Gain on disposal of assets held for sale	_	(88,536)	_
Depreciation on property, plant and equipment	6,556	3,135	2,277
Loss on disposal of property, plant and equipment	2	179	34
Impairment of property, plant and equipment	_	1,174	_
Amortization of leasehold land	164	166	271
Amortization of other intangible asset	222	225	217
Reversal provision for trade receivables	_	(81)	_
Provision for excess and obsolete inventories	994	1,236	1,569
Exchange differences	1,377	186	1,720
Changes in working capital:			
Trade and bills receivables	1,273	(463)	(4,236)
Other receivables, prepayments and deposits	(1,057)	922	361
Inventories	(14,257)	(8,395)	(7,118)
Trade payables	3,794	3,572	(5,530)
Other payables, accruals and advance receipts	13,574	3,740	25,979
Deferred income	121	(329)	(430)
Payment for other intangible asset			(1,202)
Total changes in working capital	3,448	(953)	7,824
Net cash generated from operations	78,503	64,310	51,007

# (b) Supplemental disclosure for non-cash activities

During the year ended December 31, 2017, there was a decrease in accruals made for purchases of property, plant and equipment of US\$4.3 million.

#### 21. Commitments

## (a) Capital commitments

The Group had the following capital commitments:

	December 31,
	2017 2016
	(in US\$'000)
Property, plant and equipment	
Contracted but not provided for	574

Capital commitments for property, plant and equipment are mainly for improvements to the Company's plant.

# (b) Operating lease commitments

The Group leases various factories and offices under non-cancellable operating lease agreements. The future aggregate minimum lease payments in respect of land and buildings under non-cancellable operating leases were as follows:

	Dece	December 31,		
	2017	2016		
	(in l	US\$'000)		
Not later than 1 year	283	405		
Between 1 to 2 years	21	101		
Between 2 to 3 years	10	3		
	314	509		

## 22. Significant Related Party Transactions

The Group has the following significant transactions during the years with related parties which were carried out in the normal course of business at terms determined and agreed by the relevant parties:

## (a) Transactions with related parties:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Sales of goods to:			
—A fellow subsidiary of SHTCML	27,471	26,044	17,478
—A fellow subsidiary of SHCM(HK)IL			3,549
	27,471	26,044	21,027
Purchase of goods from:			
—Fellow subsidiaries of SHTCML	16,469	17,792	11,151
Rendering of marketing services from:			
—A fellow subsidiary of SHTCML		223	389
Rendering of research and development services from:			
—A fellow subsidiary of SHCM(HK)IL	789	315	286
Provision of marketing services to:			
—A fellow subsidiary of SHCM(HK)IL	10,195	8,401	5,093

No transactions have been entered into with the directors of the Company (being the key management personnel) during the year ended December 31, 2017 (2016 and 2015: nil).

# (b) Balances with related parties included in:

	December 31,	
	2017	2016
	(in US	\$\$'000)
Trade receivables—related parties		
—A fellow subsidiary of SHTCML	399	3,943
—A fellow subsidiary of SHCM(HK)IL	6,567	3,067
	6,966	7,010
Other receivables—related parties		
—A fellow subsidiary of SHTCML	974	
Trade payable—related parties		
—A fellow subsidiary of SHTCML	2,999	1,656
Other payables, accruals and advance receipts		
—Fellow subsidiaries of SHCM(HK)IL	888	739

Balances with related parties are unsecured, interest-free and repayable on demand. The carrying values of balances with related parties approximate their fair values due to their short-term maturities.

# 23. Particulars of Principal Subsidiaries

	Place of establishment	of reg	al value istered oital	inte attrib to the	uity erest utable Group		
N.	and		ber 31,		ber 31,	T	<b>7</b> 0
Name	operation	$\frac{2017}{\text{(in RN)}}$	2016 (B'000)	2017	2016	Type of legal entity	Principal activity
Shanghai Shangyao Hutchison Whampoa GSP Company Limited	PRC	20,000	20,000	100%	100%	Limited liability company	Distribution of drug products
Hutchison Heze Bio Resources & Technology Co., Limited	PRC	1,500	1,500	100%	100%	Limited liability company	Agriculture and sales of Chinese herbs

# 24. Subsequent Events

The Group evaluated subsequent events through March 9, 2018, which is the date when the consolidated financial statements were issued.

# HUTCHISON WHAMPOA GUANGZHOU BAIYUNSHAN CHINESE MEDICINE COMPANY LIMITED

#### **Report of Independent Auditors**

## To the Board of Directors and Shareholders of Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited

We have audited the accompanying consolidated financial statements of Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited and its subsidiaries, which comprise the consolidated statements of financial position as of December 31, 2017 and 2016, and the related consolidated income statements, consolidated statements of comprehensive income, of changes in equity and of cash flows for each of the three years in the period ended December 31, 2017.

## Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

#### Auditors' Responsibility

Our responsibility is to express an opinion on the consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the Company's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited and its subsidiaries as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

/s/ PricewaterhouseCoopers Zhong Tian LLP Guangzhou, the People's Republic of China March 9, 2018

# Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited Consolidated Income Statements (in US\$'000)

		Year Ended December 31,		
	Note	2017	2016	2015
Revenue	5	227,422	224,131	211,603
Cost of sales		(135,964)	(134,776)	(120,142)
Gross profit		91,458	89,355	91,461
Selling expenses		(45,262)	(46,873)	(45,325)
Administrative expenses		(24,541)	(21,716)	(23,722)
Other net operating income	6	3,000	3,097	2,902
Operating profit	7	24,655	23,863	25,316
Share of profits of joint venture and associated		·		
companies, net of tax		65	19	6
Finance costs		(117)	(123)	(158)
Loss on divestment of a subsidiary	14	(169)		
Profit before taxation		24,434	23,759	25,164
Taxation charge	8	(3,629)	(3,631)	(3,948)
Profit for the year		20,805	20,128	21,216
Attributable to:				
Shareholders of the Company		20,776	20,376	21,376
Non-controlling interests		29	(248)	(160)
		20,805	20,128	21,216

# Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited Consolidated Statements of Comprehensive Income (in US\$'000)

	Year Ended December 31,		
	2017	2016	2015
Profit for the year	20,805	20,128	21,216
Other comprehensive income/(loss) that has been or may be reclassified subsequently to profit or loss:			
Exchange translation differences	8,293	(9,248)	(5,097)
Total comprehensive income	29,098	10,880	16,119
Attributable to:			
Shareholders of the Company	28,672	11,549	16,427
Non-controlling interests	426	(669)	(308)
	29,098	10,880	16,119

# Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited Consolidated Statements of Financial Position (in US\$'000)

Assets         Current assets         Cash and cash equivalents         10         13,843         23,448           Bank deposits maturing over three months         10         ————————————————————————————————————			Decem	nber 31,	
Current assets         10         13,843         23,448           Bank deposits maturing over three months         10         —         1,675           Trade and bills receivables         11         36,368         39,901           Other receivables, prepayments and deposits         12         6,936         3,671           Inventories         13         44,423         28,839           Assets classified as held for sale         14         —         25,097           Total current assets         101,570         122,631           Property, plant and equipment         15         70,817         65,130           Leasehold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         4,73         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015		Note	2017	2016	
Cash and cash equivalents         10         13,843         23,448           Bank deposits maturing over three months         10         —         1,675           Trade and bills receivables         11         36,368         39,901           Other receivables, prepayments and deposits         12         6,936         3,901           Inventories         13         44,423         28,839           Inventories         10,179         97,534           Assets classified as held for sale         14         —         25,097           Total current assets         101,570         122,631           Property, plant and equipment         15         70,817         65,130           Leaschold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         20,906         30,76           Total assets         20,879         221,735           Liabilities and shareholders' equity         11,366         10,504           Total assets         19         59,015         33,689           Current liabilities<	Assets				
Bank deposits maturing over three months         10         —         1,675           Trade and bills receivables         11         36,368         39,901           Other receivables, prepayments and deposits         12         6,936         3,671           Inventories         13         44,423         28,839           Assets classified as held for sale         14         —         25,097           Total current assets         101,570         122,631           Property, plant and equipment         15         70,817         65,130           Leasehold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Urrent liabilities         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,685           Other payables, accruals and advance receipts <td< td=""><td>Current assets</td><td></td><td></td><td></td></td<>	Current assets				
Trade and bills receivables         11         36,368         39,901           Other receivables, prepayments and deposits         12         6,936         3,671           Inventories         13         44,423         28,839           Assets classified as held for sale         14         —         25,097           Total current assets         101,570         122,631           Property, plant and equipment         15         70,817         65,130           Leaschold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and sharcholders' equity         8         15         5,45         18,575           Other payables         18         15,545         18,575         31,685           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities	Cash and cash equivalents	10	13,843	23,448	
Other receivables, prepayments and deposits         12         6,936         3,671           Inventories         13         44,423         28,839           Assets classified as held for sale         14         —         25,097           Total current assets         101,570         122,631           Property, plant and equipment         15         70,817         65,130           Leasehold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Total current liabilities         75,787         70,218           Deferred tax liabilities         75,787         70,218	Bank deposits maturing over three months	10	_	1,675	
Inventories	Trade and bills receivables	11		39,901	
Name   Name	Other receivables, prepayments and deposits				
Assets classified as held for sale         14         —         25,097           Total current assets         101,570         122,631           Property, plant and equipment         15         70,817         65,130           Leasehold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         1         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218           Deferred tax liabilities         75,787         70,218           Deferred tax liabilities         36         451	Inventories	13	44,423	28,839	
Total current assets         101,570         122,631           Property, plant and equipment         15         70,817         65,130           Leasehold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218           Deferred tax liabilities         18         15,545         18,246           Total labilities         45         17,566           Total liabilities         45,35         88,366 <td< td=""><td></td><td></td><td>101,570</td><td>97,534</td></td<>			101,570	97,534	
Property, plant and equipment         15         70,817         65,130           Leasehold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         8         15,545         18,575           Other payables, accruals and advance receipts         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Total current liabilities         75,787         53,156           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218         76,787         70,218           Deferred tax liabilities         386         451         114         131	Assets classified as held for sale	14	´—	25,097	
Leasehold land         10,424         10,056           Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         1         15,545         18,575           Other payables         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218         75,787         70,218           Deferred tax liabilities         16         114         131         16         114         131           Deferred income         20         18,248         17,566         176         178         176         176         178         176	Total current assets		101,570	122,631	
Goodwill         8,751         8,237           Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         8         15,545         18,575           Other payables         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         16         114         131           Deferred tax liabilities         16         114         131           Deferred income         20         18,248         17,566           Finance lease payables         386         451           Total liabilities         24,103         24,103           Reserves         86,513         102,969	Property, plant and equipment	15	70,817	65,130	
Other intangible assets         2,906         3,076           Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         8         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218         70,218           Deferred tax liabilities         16         114         131           Deferred income         20         18,248         17,566           Finance lease payables         386         451           Total liabilities         94,535         88,366           Company's shareholders' equity         24,103         24,103           Reserves         86,513         102,969           Total Company's shareholders' equity         110,616	Leasehold land		10,424	10,056	
Investments in a joint venture and associated companies         473         384           Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         Current liabilities           Trade payables         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218         70,218         16         114         131         131         131         132         133         136         451         134         131         136         136         451         134         131         136         134         131         136         136         451         136         14         131         136         136         451         136         14         131         136         136         451         136         14         136 <td>Goodwill</td> <td></td> <td>8,751</td> <td>8,237</td>	Goodwill		8,751	8,237	
Deferred tax assets         16         2,489         1,717           Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         Verify the payables of the payables of the payables, accruals and advance receipts         18         15,545         18,575         18,575         Other payables, accruals and advance receipts         19         59,015         33,689         20	Other intangible assets		2,906	3,076	
Other non-current assets         17         11,366         10,504           Total assets         208,796         221,735           Liabilities and shareholders' equity         8         15,545         18,575           Current liabilities         18         15,545         18,575         33,689         Current tax liabilities         1,227         892           Current tax liabilities         75,787         53,156         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218           Deferred tax liabilities         16         114         131           Deferred income         20         18,248         17,566           Finance lease payables         386         451           Total liabilities         94,535         88,366           Company's shareholders' equity         24,103         24,103           Reserves         86,513         102,969           Total Company's shareholders' equity         110,616         127,072           Non-controlling interests         3,645         6,297           Total shareholders' equity         114,261         133,369	Investments in a joint venture and associated companies		473	384	
Total assets         208,796         221,735           Liabilities and shareholders' equity           Current liabilities         18         15,545         18,575           Other payables, accruals and advance receipts         19         59,015         33,689           Current tax liabilities         1,227         892           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218           Deferred tax liabilities         16         114         131           Deferred income         20         18,248         17,566           Finance lease payables         386         451           Total liabilities         94,535         88,366           Company's shareholders' equity         24,103         24,103           Reserves         86,513         102,969           Total Company's shareholders' equity         110,616         127,072           Non-controlling interests         3,645         6,297           Total shareholders' equity         114,261         133,369	Deferred tax assets	16	2,489	1,717	
Liabilities and shareholders' equity           Current liabilities         18 15,545 18,575           Other payables, accruals and advance receipts         19 59,015 33,689           Current tax liabilities         1,227 892           Liabilities directly associated with assets classified as held for sale         14 — 17,062           Total current liabilities         75,787 70,218           Deferred tax liabilities         16 114 131           Deferred income         20 18,248 17,566           Finance lease payables         386 451           Total liabilities         94,535 88,366           Company's shareholders' equity         24,103 24,103           Reserves         86,513 102,969           Total Company's shareholders' equity         110,616 127,072           Non-controlling interests         3,645 6,297           Total shareholders' equity         114,261 133,369	Other non-current assets	17	11,366	10,504	
Current liabilities       18       15,545       18,575         Other payables, accruals and advance receipts       19       59,015       33,689         Current tax liabilities       1,227       892         Total current liabilities       75,787       53,156         Liabilities directly associated with assets classified as held for sale       14       —       17,062         Total current liabilities       75,787       70,218         Deferred tax liabilities       16       114       131         Deferred income       20       18,248       17,566         Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Total assets		208,796	221,735	
Current liabilities       18       15,545       18,575         Other payables, accruals and advance receipts       19       59,015       33,689         Current tax liabilities       1,227       892         Total current liabilities       75,787       53,156         Liabilities directly associated with assets classified as held for sale       14       —       17,062         Total current liabilities       75,787       70,218         Deferred tax liabilities       16       114       131         Deferred income       20       18,248       17,566         Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Liabilities and shareholders' equity				
Other payables, accruals and advance receipts       19       59,015       33,689         Current tax liabilities       1,227       892         Liabilities directly associated with assets classified as held for sale       14       —       17,062         Total current liabilities       75,787       70,218         Deferred tax liabilities       16       114       131         Deferred income       20       18,248       17,566         Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369					
Current tax liabilities         1,227         892           T5,787         53,156           Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218           Deferred tax liabilities         16         114         131           Deferred income         20         18,248         17,566           Finance lease payables         386         451           Total liabilities         94,535         88,366           Company's shareholders' equity         24,103         24,103           Reserves         86,513         102,969           Total Company's shareholders' equity         110,616         127,072           Non-controlling interests         3,645         6,297           Total shareholders' equity         114,261         133,369	Trade payables	18	15,545	18,575	
Liabilities directly associated with assets classified as held for sale       14       —       17,062         Total current liabilities       75,787       70,218         Deferred tax liabilities       16       114       131         Deferred income       20       18,248       17,566         Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Other payables, accruals and advance receipts	19	59,015	33,689	
Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218           Deferred tax liabilities         16         114         131           Deferred income         20         18,248         17,566           Finance lease payables         386         451           Total liabilities         94,535         88,366           Company's shareholders' equity         24,103         24,103           Reserves         86,513         102,969           Total Company's shareholders' equity         110,616         127,072           Non-controlling interests         3,645         6,297           Total shareholders' equity         114,261         133,369	Current tax liabilities		1,227	892	
Liabilities directly associated with assets classified as held for sale         14         —         17,062           Total current liabilities         75,787         70,218           Deferred tax liabilities         16         114         131           Deferred income         20         18,248         17,566           Finance lease payables         386         451           Total liabilities         94,535         88,366           Company's shareholders' equity         24,103         24,103           Reserves         86,513         102,969           Total Company's shareholders' equity         110,616         127,072           Non-controlling interests         3,645         6,297           Total shareholders' equity         114,261         133,369			75,787	53,156	
Deferred tax liabilities       16       114       131         Deferred income       20       18,248       17,566         Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Liabilities directly associated with assets classified as held for sale	14			
Deferred tax liabilities       16       114       131         Deferred income       20       18,248       17,566         Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Total current liabilities		75,787	70,218	
Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity         Share capital         Reserves         24,103         24,103         102,969      102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369		16			
Finance lease payables       386       451         Total liabilities       94,535       88,366         Company's shareholders' equity       24,103       24,103         Share capital       24,103       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Deferred income	20	18,248	17,566	
Company's shareholders' equity         24,103         24,103           Share capital         24,103         24,103           Reserves         86,513         102,969           Total Company's shareholders' equity         110,616         127,072           Non-controlling interests         3,645         6,297           Total shareholders' equity         114,261         133,369	Finance lease payables				
Share capital       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Total liabilities		94,535	88,366	
Share capital       24,103       24,103         Reserves       86,513       102,969         Total Company's shareholders' equity       110,616       127,072         Non-controlling interests       3,645       6,297         Total shareholders' equity       114,261       133,369	Company's shareholders' equity				
Reserves         86,513         102,969           Total Company's shareholders' equity         110,616         127,072           Non-controlling interests         3,645         6,297           Total shareholders' equity         114,261         133,369			24,103	24,103	
Non-controlling interests3,6456,297Total shareholders' equity114,261133,369	•				
Non-controlling interests3,6456,297Total shareholders' equity114,261133,369	Total Company's shareholders' equity		110,616	127,072	
Total liabilities and shareholder's equity 208,796 221,735	Total shareholders' equity		114,261	133,369	
	Total liabilities and shareholder's equity		208,796	221,735	

# Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited Consolidated Statements of Changes in Equity (in US\$'000)

	Attributable to shareholders of the Company			Non-			
	Share capital	Exchange reserve	General reserves	Retained earnings	Total	controlling interests	Total equity
As at January 1, 2015	24,103	12,592	131	74,680	111,506	3,802	115,308
Profit/(loss) for the year	· —	_	_	21,376	21,376	(160)	21,216
Other comprehensive loss							
Exchange translation differences		(4,949)			(4,949)	(148)	(5,097)
Total comprehensive (loss)/ income		(4,949)		21,376	16,427	(308)	16,119
Dividends declared to shareholders	_	_	_	(6,410)	(6,410)	_	(6,410)
Capital contribution from a non-controlling shareholder of a subsidiary						46	46
As at December 31, 2015	24,103	7,643	131	89,646	121,523	3,540	125,063
Profit/(loss) for the year Other comprehensive loss	_	_	_	20,376	20,376	(248)	20,128
Exchange translation differences		(8,827)			(8,827)	(421)	(9,248)
Total comprehensive (loss)/income		(8,827)		20,376	11,549	(669)	10,880
Dividends declared to shareholders	_	_	_	(6,000)	(6,000)	_	(6,000)
Dividend declared to a non-controlling shareholder of a subsidiary	_	_	_	_	_	(174)	(174)
Capital contribution from a non-controlling shareholder of a subsidiary	_	_	_	_	_	3,600	3,600
As at December 31, 2016	24,103	(1,184)	131	104,022	127,072	6,297	133,369
Profit for the year Other comprehensive income	_	_	_	20,776	20,776	29	20,805
Exchange translation differences	_	7,896	_	_	7,896	397	8,293
Total comprehensive income		7,896		20,776	28,672	426	29,098
Dividends declared to shareholders	_	_	_	(45,128)	(45,128)	_	(45,128)
Divestment of a subsidiary						(3,078)	(3,078)
As at December 31, 2017	24,103	6,712	131	79,670	110,616	3,645	114,261

# Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited Consolidated Statements of Cash Flows (in US\$'000)

		Year Ended Decembe		
	Note	2017	2016	2015
Operating activities				
Net cash generated from operations	21(a)	24,844	16,426	12,278
Interest received		220	238	628
Finance costs paid		(117)	(412)	(36)
Income tax paid		(4,040)	(4,159)	(4,703)
Net cash generated from operating activities		20,907	12,093	8,167
Investing activities				
Purchase of property, plant and equipment		(7,236)	(13,219)	(21,698)
Deposits into bank deposits maturing over three months		_	(1,466)	(3,178)
Proceed from bank deposits maturing over three months		1,780	53	23,749
Government grants received relating to property, plant and				
equipment		660	3,733	451
Proceeds from divestment of a subsidiary, net of cash held	14	2,641		
Net cash used in investing activities		(2,155)	(10,899)	(676)
Financing activities				
Dividends paid to shareholders		(29,872)	(6,000)	(6,410)
Finance lease payments		(93)	_	
Proceeds from bank borrowings		_	_	923
Repayment of bank borrowings		_	(923)	(625)
Capital contribution from a non-controlling shareholder of a				
subsidiary				46
Net cash used in financing activities		(29,965)	(6,923)	(6,066)
Net (decrease)/increase in cash and cash equivalents		(11,213)	(5,729)	1,425
Effect of exchange rate changes on cash and cash equivalents		1,474	(1,844)	(1,274)
		(9,739)	(7,573)	151
Cash and cash equivalents				
Cash and cash equivalents at beginning of year		23,582	31,155	31,004
Cash and cash equivalents at end of year		13,843	23,582	31,155

## Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited Notes to the Consolidated Financial Statements

#### 1. General Information

Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine Company Limited (the "Company") and its subsidiaries (together the "Group") are principally engaged in manufacturing, selling and distribution of over-the-counter drug products. The Group has manufacturing plants in the People's Republic of China (the "PRC") and sells mainly in the PRC.

The Company was incorporated in the PRC on April 12, 2005 as a Chinese-Foreign Equity joint venture. The Company is jointly controlled by Guangzhou Hutchison Chinese Medicine (HK) Investment Limited ("GZHCMHK") and Guangzhou Baiyunshan Pharmaceutical Holdings Company Limited ("GBPHCL").

These consolidated financial statements are presented in United States dollars ("US\$"), unless otherwise stated and have been approved for issue by the Company's Board of Directors on March 9, 2018.

#### 2. Summary of Significant Accounting Policies

The consolidated financial statements of the Company have been prepared in accordance with International Financial Reporting Standards ("IFRS") and interpretations issued by the IFRS Interpretations Committee applicable to companies reporting under IFRS. The consolidated financial statements comply with IFRS as issued by the International Accounting Standards Board ("IASB"). These consolidated financial statements have been prepared under the historical cost convention.

During the year, the Group has adopted all of the new standards, amendments and interpretations issued by the IASB that are relevant to the Group's operations and mandatory for annual periods beginning January 1, 2017. The adoption of these new standards, amendments and interpretations did not have any material effects on the Group's results of operations or financial position.

The following standards, amendments and interpretations were in issue but not yet effective for financial year ended December 31, 2017 and have not been early adopted by the Group:

IAS 28 (Amendments) <sup>(1)</sup>	Investments in Associates and Joint Ventures
IAS 40 (Amendments) <sup>(1)</sup>	Transfers of Investment Property
IFRS 2 (Amendments) <sup>(1)</sup>	Classification and Measurement of Share-based
	Payment Transactions
IFRS 9 <sup>(1)</sup>	Financial Instruments
IFRS 10 and IAS 28 (Amendments) <sup>(3)</sup>	Sale or Contribution of Assets between an
	Investor and its Associate or Joint Venture
IFRS 15 <sup>(1)</sup>	Revenue from Contracts with Customers
IFRS 15 (Amendments) <sup>(1)</sup>	Revenue from Contracts with Customers
IFRS 16 <sup>(2)</sup>	Leases
IFRIC 22 <sup>(1)</sup>	Foreign Currency Transactions and Advance
	Consideration
IFRIC 23 <sup>(2)</sup>	Uncertainty over Income Tax Treatments
Annual improvement 2014-2016 <sup>(1)</sup>	Improvements to IFRSs
Annual improvement 2015-2017 <sup>(2)</sup>	Improvements to IFRSs

- (1) Effective for the Group for annual periods beginning on or after January 1, 2018.
- (2) Effective for the Group for annual periods beginning on or after January 1, 2019.

### (3) No mandatory effective date determined yet, but available for adoption.

The adoption of standards, amendments and interpretations listed above in future periods is not expected to have any material effects on the Group's results of operations and financial position, except for the adoption of IFRS 16 for which management is still assessing the impact.

Based on its evaluation of IFRS 15 and its Amendments, the Group expects there will not be a material impact to the timing of revenue recognition. The Group expects the timing of recognition will be at the point when the goods have been transferred to the customer and the customer obtains control of the goods as evidenced by delivery of the product, transfer of title and when no further obligations to the customer remain. The Group will adopt the new standard using the modified retrospective method in the year commencing January 1, 2018.

#### (a) Basis of Consolidation

The consolidated financial statements of the Group include the financial statements of the Company and its subsidiaries, and also include the Group's interests in a joint venture and associated companies on the basis set out in Notes 2(e) and 2(f) below.

The accounting policies of subsidiaries, the joint venture and associated companies have been changed where necessary to ensure consistency with the policies adopted by the Group.

Intercompany transactions, balances and unrealized gains on transactions between group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

Non-controlling interests represent the interests of outside shareholders in the operating results and net assets of subsidiaries.

#### (b) Subsidiaries

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. In the consolidated financial statements, subsidiaries are accounted for as described in Note 2(a) above.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

#### (c) Business Combinations

The Group applies the acquisition method to account for business combinations. The consideration transferred for the acquisition of a subsidiary is the fair values of the assets transferred, the liabilities incurred to the former owners of the acquiree and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date.

The Group recognizes any non-controlling interest in the acquiree on an acquisition-by-acquisition basis. Non-controlling interests in the acquiree that are present ownership interests and entitle their holders to a proportionate share of the entity's net assets in the event of liquidation are measured at either fair value or the present ownership interests' proportionate share in the recognized amounts of the acquiree's identifiable net assets. All other components of non-controlling interests are measured at their acquisition date fair value, unless another measurement basis is required by IFRS.

Acquisition-related costs are expensed as incurred.

The excess of the consideration transferred over the fair value of the identifiable net assets acquired is recorded as goodwill. If the total of consideration transferred, non-controlling interest recognized and previously held interest measured is less than the fair value of the net assets of the acquiree acquired in the case of a bargain purchase, the difference is recognized directly in the income statement.

#### (d) Transactions with Non-controlling Interests

Transactions with non-controlling interests that do not result in a loss of control are accounted for as transactions with equity owners of the Group. For purchases from non-controlling interests, the difference between any consideration paid and the relevant share acquired of the carrying value of net assets of the subsidiary is recorded in equity. Gains or losses on disposals to non-controlling interests are also recorded in equity.

## (e) Joint Arrangements

Investments in joint arrangements are classified either as joint operations or joint ventures depending on the contractual rights and obligations of each investor. The Group has assessed the nature of its joint arrangement and determined it to be a joint venture. The joint venture is accounted for using the equity method.

Under the equity method of accounting, the interest in joint venture is initially recognized at cost and adjusted thereafter to recognize the Group's share of the post-acquisition profits or losses and movements in other comprehensive income. The Group determines at each reporting date whether there is any objective evidence that the investment in the joint venture is impaired. If this is the case, the Group calculates the amount of impairment as the difference between the recoverable amount of the joint venture and its carrying value and recognizes the amount adjacent to "share of profits less losses after tax of joint venture" in the income statement.

#### (f) Associated Companies

An associate is an entity, other than a subsidiary or a joint venture, in which the Group has a long-term equity interest and over which the Group is in position to exercise significant influence over its management, including participation in the financial and operating policy decisions.

The results and net assets of associates are incorporated in these financial statements using the equity method of accounting, except when the investment is classified as held for sale, in which case it is accounted for under IFRS 5, Non-current assets held for sale and discontinued operations. The total carrying amount of such investments is reduced to recognize any identified impairment loss in the value of individual investments.

#### (g) Foreign Currency Translation

Items included in the financial statements of each of the Group's companies are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The functional currency of the Company and its subsidiaries, joint venture and associated companies is Renminbi ("RMB") whereas the consolidated financial statements are presented in US\$, which is the Company's presentation currency.

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign currency gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in the income statement.

The financial statements of the Company, subsidiaries, joint venture and associated companies are translated into the Company's presentation currency using the year end rates of exchange for the

statements of financial position items and the average rates of exchange for the year for the income statement items. Exchange translation differences are recognized directly in other comprehensive income/(loss).

## (h) Property, Plant and Equipment

Property, plant and equipment other than construction in progress are stated at historical cost less accumulated depreciation and any accumulated impairment losses. Historical cost includes the purchase price of the asset and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate asset costs less accumulated impairment losses over their estimated useful lives. The principal estimated useful lives are as follows:

Buildings and facilities	10-30 years
Plant and equipment	10 years
Furniture and fixtures, other equipment and motor vehicles	5 years

The assets' useful lives are reviewed and adjusted, if appropriate, at the end of each reporting period. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing net sales proceeds with the carrying amount of the relevant assets and are recognized in the income statement.

#### (i) Construction in Progress

Construction in progress represents buildings, plant and machinery under construction and pending installation and is stated at cost less accumulated impairment losses, if any. Cost includes the costs of construction of buildings and the costs of plant and machinery. No provision for depreciation is made on construction in progress until such time as the relevant assets are completed and ready for intended use. When the assets concerned are brought into use, the costs are transferred to property, plant and equipment and depreciated in accordance with the policy as stated in Note 2(h).

#### (j) Leasehold Land

Leasehold land is stated at cost less accumulated amortization and accumulated impairment losses, if any. Cost mainly represents consideration paid for the rights to use the land on which various plants and buildings are situated for a period of 50 years from the date the respective right was granted. Amortization of leasehold land is calculated on a straight-line basis over the period of the land use rights.

## (k) Goodwill

Goodwill represents the excess of the cost of an acquisition over the fair value of the Group's share of the net identifiable assets of the acquired subsidiary/business at the date of acquisition, or the excess of fair value of business over its fair value of the net identifiable assets injected into the Company upon its formation. If the cost of acquisition is less than the fair value of the Group's share of the net identifiable assets of the acquired subsidiary, the difference is recognized directly in the consolidated income statement.

Goodwill is retained at the carrying amount as a separate asset, and subject to impairment test annually when there are indications that the carrying value may not be recoverable.

The profit or loss on disposal of a subsidiary is calculated by reference to the net assets at the date of disposal including the attributable amount of goodwill.

#### (l) Other Intangible Assets

The Group's other intangible assets mainly include distribution network and drugs licenses contributed from non-controlling shareholders. Other intangible assets have a definite useful life and are carried at historical cost less accumulated amortization and accumulated impairment losses, if any. Amortization is calculated using the straight-line method to allocate costs over the estimated useful lives of ten years.

# (m) Research and Development

Research expenditure is recognized as an expense as incurred. Costs incurred on development projects (relating to the design and testing of new or improved products) are recognized as intangible assets when it is probable that the project will generate future economic benefits by considering its commercial and technological feasibility, and costs can be measured reliably. Other development expenditures are recognized as an expense as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period. Development costs with a finite useful life that have been capitalized, if any, are amortized on a straight-line basis over the period of expected benefit not exceeding five years. The capitalized development costs are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset exceeds its recoverable amount.

Where the research phase and the development phase of an internal project cannot be clearly distinguished, all expenditure incurred on the project is charged to the income statement.

## (n) Impairment of Non-Financial Assets

Assets that have an indefinite useful life such as goodwill or intangible assets not ready to use are not subject to amortization and are tested for impairment annually. Assets are reviewed for impairment to determine whether there is any indication that the carrying value of these assets may not be recoverable and have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss, if any. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. Such impairment loss is recognized in the income statement.

#### (o) Non-current Assets (or Disposal Groups) Classified As Held For Sale

Non-current assets (or disposal groups) are classified as held for sale when their carrying amount is to be recovered principally through a sale transaction and a sale is considered highly probable. The non-current assets (or disposal groups) except for certain assets as explained below, are stated at the lower of carrying amount and fair value less costs to sell. Deferred tax assets, and financial assets (other than investments in subsidiaries and associates), which are classified as held for sale, would continue to be measured in accordance with the policies set out elsewhere in Note 2.

# (p) Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the weighted average cost method. The cost of finished goods comprises raw materials, direct labor, other direct costs and related production overheads (based on normal operating capacity). Net realizable value is the estimated selling price in the ordinary course of business, less applicable variable selling expenses.

#### (q) Trade and Other Receivables

Trade and other receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less provision for impairment. A provision for impairment of trade and other receivables is established when there is objective evidence that the asset is impaired. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the effective interest rate. The amount of the provision is recognized in the income statement.

## (r) Cash and Cash Equivalents

In the consolidated statements of cash flows, cash and cash equivalents include cash on hand, bank deposits and other short-term highly liquid investments with original maturities of three months or less and restricted cash.

#### (s) Borrowings

Borrowings are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method.

## (t) Financial Liabilities and Equity Instruments

Financial liabilities and equity instruments issued by the Group are classified according to the substance of the contractual arrangements entered into and the definitions of a financial liability and an equity instrument. Financial liabilities (including trade and other payables) are initially measured at fair value, and are subsequently measured at amortized cost, using the effective interest method. An equity instrument is any contract that does not meet the definition of financial liability and evidences a residual interest in the assets of the Group after deducting all of its liabilities.

Ordinary shares are classified as equity. Incremental costs, net of tax, directly attributable to the issue of new shares are shown in equity as a deduction from the proceeds.

#### (u) Current and Deferred Income Tax

#### (i) Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the country where the Group operates and generates taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

### (ii) Deferred income tax

## Inside basis differences

Deferred income tax is recognized, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill and deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws)

that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

## Outside basis differences

Deferred income tax liabilities are provided on taxable temporary differences arising from investments in subsidiaries, associates and joint arrangements, except for deferred income tax liabilities where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future. Generally the Group is unable to control the reversal of the temporary difference for associates. Only when there is an agreement in place that gives the Group the ability to control the reversal of the temporary difference in the foreseeable future, deferred tax liability in relation to taxable temporary differences arising from the associate's undistributed profits is not recognized.

Deferred income tax assets are recognized on deductible temporary differences arising from investments in subsidiaries, associates and joint arrangements only to the extent that it is probable the temporary difference will reverse in the future and there is sufficient taxable profit available against which the temporary difference can be utilized.

## (v) Employee Benefits

The employees of the Group participate in defined contribution retirement benefit plans managed by the relevant municipal and provincial governments in the PRC. The assets of these plans are held separately from those of the Group. The Group is required to make monthly contributions to the plans, calculated as a percentage of the employees' salaries. The municipal and provincial governments undertake to assume the retirement benefit obligations to all existing and future retired employees under the plans described above. Other than the monthly contributions, the Group has no further obligations for the payment of the retirement and other post-retirement benefits of its employees.

## (w) Provisions

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events; it is probable that an outflow of resources will be required to settle the obligation; and the amount has been reliably estimated. Provisions are not recognized for future operating losses.

#### (x) Leases

Leases that transfer substantially all the rewards and risks of ownership of the assets to the Group, other than legal title, are accounted for as finance leases. At the inception of a finance lease, the cost of the leased asset is capitalized at the present value of the minimum lease payments and recorded together with the obligation, excluding the interest element, to reflect the purchase and financing. Assets held under capitalized finance leases, including prepaid land lease payments under finance leases, are included in property, plant and equipment, and depreciated over the shorter of the lease terms and the estimated useful lives of the assets. The finance costs of such leases are charged to the income statement so as to provide a constant periodic rate of charge over the lease terms.

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the income statement on a straight-line basis over the period of the leases.

#### (y) Borrowing Costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, which are assets that necessarily take a substantial period of time to get ready for their intended use or sale, are added to the cost of those assets, until such time as the assets are substantially ready for their intended use or sale. All other borrowing costs are recognized in the income statement in the period in which they are incurred.

#### (z) Government Incentives

Incentives from government are recognized at their fair values where there is a reasonable assurance that the incentives will be received and all attached conditions will be complied with.

Government incentives relating to costs are deferred and recognized in the income statement over the period necessary to match them with the costs that they are intended to compensate.

Government grants relating to property, plant and equipment are included in other payables, accruals and advance receipts and non-current liabilities as deferred income and credited to the income statement on a straight-line basis over the expected lives of the related assets.

#### (aa) Revenue and Income Recognition

Revenue comprises the fair value of the consideration received and receivable for the sales of goods in the ordinary course of the Group's activities. The Group recognizes revenue when the amount of revenue can be reliably measured; when it is probable that future economic benefits will flow to the entity; and when specific criteria have been met for each of the Group's activities, as described below.

Revenue is shown net of value-added tax, returns, volume rebates and discounts after eliminated sales within the Group. Revenue and income are recognized as follows:

## (i) Sales of goods

Sales of goods are recognized when a group entity has delivered products to the customer, the customer has accepted the products and collectability of the related receivables is reasonably assured.

#### (ii) Sales rebates

Certain sales rebates are provided to customers when their business performance for the whole year meets certain criteria. Sales rebates are recognized in profit or loss based on management's estimation at each year end.

#### (iii) Other service income

Other service income is recognized when services are rendered.

#### (iv) Interest income

Interest income is recognized on a time-proportion basis using the effective interest method.

#### (ab) Segment Reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-makers. The Board of Directors, which is responsible for allocating resources and assessing performance of the operating segments, has been identified as the steering committee that makes strategic decisions.

#### (ac) General Reserves

In accordance with the laws applicable to Foreign Investment Enterprises established in the PRC, the Company makes appropriations to certain non-distributable reserve funds including the general reserve fund, the enterprise expansion fund and the staff bonus and welfare fund. The amount of appropriations to these funds are made at the discretion of the Company's Board of Directors.

#### 3. Financial Risk Management

#### (a) Financial risk factors

The Group's activities expose it to a variety of financial risks, including credit risk, cash flow interest rate risk and liquidity risk. The Group does not use any derivative financial instruments for speculative purposes.

#### (i) Credit risk

The carrying amounts of cash at bank, bank deposits, trade receivables (including bills receivables) and other receivables included in the consolidated statements of financial position represent the Group's maximum exposure to credit risk of the counterparty in relation to its financial assets.

Substantially all of the Group's cash at banks and bank deposits are deposited in major financial institutions, which management believes are of high credit quality.

Bills receivables are mostly settled by state-owned banks or other reputable banks and therefore the management considers that they will not expose the Group to any significant credit risk.

The Group has no significant concentrations of credit risk. The Group has policies in place to ensure that the sales of products are made to customers with appropriate credit history and the Group performs periodic credit evaluations of its customers.

Management periodically assesses the recoverability of trade receivables and other receivables. The Group's historical experience collecting receivables falls within the recorded allowances.

#### (ii) Cash flow interest rate risk

The Group has no significant interest-bearing assets except for cash at bank and bank deposits, details of which have been disclosed in Note 10. The Group's exposure to interest rate risk would mainly be to bank borrowings which bear interest at fixed rates.

#### (iii) Liquidity risk

Prudent liquidity management implies maintaining sufficient cash and cash equivalents and the availability of funding when necessary. The Group's policy is to regularly monitor current and expected liquidity requirements to ensure that it maintains sufficient cash balances and adequate credit facilities to meet its liquidity requirements in the short and long term.

As at December 31, 2017 and 2016, the Group's current financial liabilities were mainly due for settlement within twelve months and the Group expects to meet all liquidity requirements.

#### (b) Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group regularly reviews and manages its capital structure to ensure an optimal balance between higher shareholders' return that might be possible with higher levels of borrowings and the advantages and security afforded by a sound capital position, and makes adjustments to the capital structure in light of changes in economic conditions.

The Group monitors capital on the basis of the liabilities to assets ratio. This ratio is calculated as total liabilities divided by total assets as shown on the consolidated statements of financial position.

Currently, it is the Group's strategy to maintain a reasonable liabilities to assets ratio. The liabilities to assets ratio as at December 31, 2017 and 2016 was as follows:

	Decem	ber 31,
	2017	2016
	(in US	\$'000)
Total liabilities	94,535	88,366
Total assets	208,796	221,735
Liabilities to assets ratio	45.3%	39.9%

#### (c) Fair value estimation

The Group does not have any financial assets or liabilities which are carried at fair value. The carrying amounts of the Group's current financial assets, including cash and bank balances, trade and bills receivables, other receivables and current financial liabilities, including trade payables, and other payables and accruals approximate their fair values due to their short-term maturities. The carrying amounts of the Group's financial instruments carried at cost or amortized cost are not materially different from their fair values.

The face values less any estimated credit adjustments for financial assets and liabilities with a maturity of less than one year are assumed to approximate their fair values. The fair value of financial liabilities for disclosure purposes is estimated by discounting the future contractual cash flows at the current market interest rate that is available to the Group for similar financial instruments.

#### 4. Critical Accounting Estimates and Judgements

Note 2 includes a summary of the significant accounting policies used in the preparation of the financial statements. The preparation of financial statements often requires the use of judgements to select specific accounting methods and policies from several acceptable alternatives. Furthermore, significant estimates and assumptions concerning the future may be required in selecting and applying those methods and policies in the financial statements. The Group bases its estimates and judgements on historical experience and various other assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates and judgements under different assumptions or conditions.

The following is a review of the more significant assumptions and estimates, as well as the accounting policies and methods used in the preparation of the consolidated financial statements.

## (a) Sales rebates

Certain sales rebates are provided to customers when their business performance for the whole year meets certain criteria as stipulated in the contracts. The estimate of sales rebates during the year is based on estimated sales transactions for the entire period stipulated and is subject to change based on actual performance and collection status.

#### (b) Useful lives of property, plant and equipment

The Group has made substantial investments in property, plant and equipment. Changes in technology or changes in the intended use of these assets may cause the estimated period of use or value of these assets to change.

## (c) Impairment of non-Financial assets

The Group tests annually whether goodwill has suffered any impairment. Other non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset exceeds its recoverable amount in accordance with the accounting policy stated in Note 2(n). The recoverable amount of an asset or a cash-generating unit is determined based on the higher of the asset's or the cash-generating unit's fair value less costs to disposal and value-in-use. The value-in-use calculation requires the entity to estimate the future cash flows expected to arise from the asset and a suitable discount rate in order to calculate present value, and the growth rate assumptions in the cash flow projections which has been prepared on the basis of management's assumptions and estimates.

### (d) Impairment of receivables

The Group makes provision for impairment of receivables based on an assessment of the recoverability of the receivables. This assessment is based on the credit history of the relevant counterparty and the current market condition. Provisions are made where events or changes in circumstances indicate that the receivables may not be collectible. The identification of impairment in receivables requires the use of judgement and estimates. Where the expectation is different from the original estimate, such difference will impact the carrying amount of receivables and impairment is recognized in the period in which such estimate has been changed.

#### (e) Deferred income tax

Deferred tax is recognized using the liability method on temporary differences arising between the tax bases of assets and liabilities against which the deductible temporary differences and the carry forward of unused tax losses and tax credits can be utilized. Where the final outcomes are different from the estimations, such differences will impact the carrying amount of deferred tax in the period in which such determination is made.

#### 5. Revenue and Segment Information

Management has reviewed the Group's internal reporting in order to assess performance and allocate resources, and has determined that the Group has two reportable operating segments as follows:

- —Manufacturing business—manufacture and distribution of drug products
- —Distribution business—provision of sales, distribution and marketing services to pharmaceutical manufacturers

The operating segments are strategic business units that offer different products and services. They are managed separately because each business requires different technology and marketing approaches. The performance of each of the reportable segments is assessed based on a measure of earnings before share of profits of joint venture and associated companies, net of tax, interest income, finance costs and taxation charge ("Adjusted EBIT").

The segment information for the reportable segments for the year is as follows:

	Year Ended December 31, 2017		
	Manufacturing business	Distribution business	
	PRC	PRC	Total
		(in US\$'000)	
Revenue from external customers	176,134	51,288	227,422
Adjusted EBIT	23,280	1,155	24,435
Interest income	131	89	220
Operating profit	23,411	1,244	24,655
Share of profits of joint venture and associated			
companies, net of tax	65	_	65
Finance costs	117		117
Loss on divestment of a subsidiary	169	_	169
Depreciation/amortization	4,976	9	4,985
Additions to non-current assets (other than financial			
instrument and deferred tax assets)	6,111	1	6,112
	As	at December 31, 201	7
T-4-1	105 125	(in US\$'000)	200.706
Total segment assets	195,135	13,661	208,796
	Year E	nded December 31, 2	2016
	Manufacturing business	Distribution business	
	PRC	PRC	Total
		(in US\$'000)	
Revenue from external customers	155,838	68,293	224,131
Adjusted EBIT	23,077	548	23,625
Interest income	160	78	238
Operating profit	23,237	626	23,863
Share of profits of joint venture and associated			
companies, net of tax	19	_	19
Finance costs	123		123
Depreciation/amortization	2,902	56	2,958
Impairment of property, plant and equipment	-,- 0-		
	617	_	617
Additions to non-current assets (other than financial		<u>—</u>	617
			20,924
Additions to non-current assets (other than financial	20,924		20,924
Additions to non-current assets (other than financial	20,924	at December 31, 2010 (in US\$'000)	20,924

	Year Ended December 31, 2015		
	Manufacturing business	Distribution business	
	PRC	PRC	Total
		(in US\$'000)	
Revenue from external customers	144,510	67,093	211,603
Adjusted EBIT	24,152	536	24,688
Interest income	496	132	628
Operating profit	24,648	668	25,316
Share of profits of joint venture and associated			
companies, net of tax	6	_	6
Finance costs	158		158
Depreciation/amortization	3,221	53	3,274
Additions to non-current assets (other than financial			
instrument and deferred tax assets)	21,698		21,698

Revenue from external customers is after elimination of inter-segment sales. The amount eliminated was US\$3,039,000 for 2017 (2016: US\$16,181,000; 2015: US\$19,010,000).

Sales between segments are carried out at mutually agreed terms.

A reconciliation of Adjusted EBIT for reportable segments to profit before taxation is provided as follows:

	Year Ended December 31,			
	2017	2016	2015	
		(in US\$'000)		
Adjusted EBIT for reportable segments	24,435	23,625	24,688	
Interest income	220	238	628	
Share of profits of joint venture and associated				
companies, net of tax	65	19	6	
Finance costs	(117)	(123)	(158)	
Loss on divestment of a subsidiary	(169)			
Profit before taxation	24,434	23,759	25,164	

# 6. Other Net Operating Income

	Year Ended December 31,			
	2017 2016		2015	
Interest income	220	238	628	
Other operating income	3,306	3,435	2,574	
Other operating expenses	(526)	(576)	(300)	
	3,000	3,097	2,902	

# 7. Operating Profit

Yea	Year Ended December 31,			
2017	2017 2016			
	(in US\$'000)			
24,655	23,863	25,316		
	2017	2017 2016 (in US\$'000)		

Operating profit is stated after charging the following:

	Year Ended December 31,		
	2017	2016	2015
	(	in US\$'000)	
Cost of inventories recognized as expense	125,156	122,969	111,064
Depreciation of property, plant and equipment	4,380	2,227	2,877
Impairment of property, plant and equipment	_	617	_
Loss on disposal of property, plant and equipment	166	60	54
Amortization of leasehold land	253	255	271
Amortization of other intangible assets	352	476	126
Operating lease rentals in respect of land and buildings	1,214	872	1,022
Movements on the provision for trade receivables	(41)	38	77
Movements on the provision for excess and obsolete			
inventories	187	972	340
Research and development expense	1,014	1,098	1,284
Auditor's remuneration	87	90	89
Employee benefit expenses (Note 9)	32,659	31,910	31,838

# 8. Taxation Charge

	Year Er	Year Ended December 31,			
	2017	2017 2016			
	(	(in US\$'000)			
Current tax	4,298	4,518	4,034		
Deferred income tax (Note 16)	(669)	(887)	(86)		
Taxation charge	3,629	3,631	3,948		

The taxation charge on the Group's profit before taxation differs from the theoretical amount that would arise using the Group's weighted average tax rate as follows:

	Year Ended December 31,		
	2017	2016	2015
	(i	in US\$'000)	
Profit before taxation	24,434	23,759	25,164
Tax calculated at the statutory tax rates of respective			
companies	6,109	5,940	6,291
Tax effects of:			
Expenses not deductible for tax purposes	70	244	207
Tax concession (note)	(2,935)	(2,783)	(2,699)
Tax losses for which no deferred tax assets were			
recognized	396	250	131
Others	(11)	(20)	18
Taxation charge	3,629	3,631	3,948

Note: The Company has been successful in its application to renew the High and New Technology Enterprise status. Accordingly, the Company is subjected to a preferential income tax rate of 15% for 2017 and up to 2019 (2016: 15%; 2015: 15%).

The weighted average tax rate calculated at the statutory tax rates of respective companies for the year was 25% (2016: 25%; 2015: 25%). The effective tax rate for the year was 14.9% (2016: 15.3%; 2015: 15.7%).

## 9. Employee Benefit Expenses

	Year	Year Ended December 31,			
	2017	2016	2015		
		(in US\$'000)			
Wages, salaries and bonuses	23,700	23,490	22,902		
Pension costs—defined contribution plans	7,637	7,417	7,695		
Staff welfare	1,322	1,003	1,241		
	32,659	31,910	31,838		

Employee benefit expenses of approximately US\$9,122,000 (2016: US\$8,704,000; 2015: US\$8,611,000) are included in cost of sales.

## 10. Cash and Bank Balances

	December 31,	
	2017	2016
	(in US	\$'000)
Cash and cash equivalents	13,843	23,582
Included in assets classified as held for sale (Note 14)		(134)
Cash and cash equivalents as per consolidated statements of		
financial position	13,843	23,448
Bank deposits maturing over three months (note)		1,675
Cash and bank balances	13,843	25,123

Note: The weighted average effective interest rate on bank deposits as at December 31, 2016 with maturity of 91 days to 365 days was 1.3% per annum. Cash at bank earns interest at floating rates based on daily bank deposit rates.

The cash at bank balances are denominated in RMB and were deposited with banks in the PRC. The conversion of these RMB denominated balances into foreign currencies is subject to the rules and regulations of foreign exchange control promulgated by the PRC government.

## 11. Trade and Bills Receivables

	Decem	ber 31,
	2017	2016
	(in US	<b>\$</b> '000)
Trade receivables—third parties	1,755	223
Trade receivables—related parties (Note 23(b))	285	466
Bills receivables	34,328	39,212
	36,368	39,901

All trade and bills receivables are denominated in RMB and are due within one year from the end of the reporting period. The carrying value of trade and bills receivables approximates their fair values.

Movements on the provision for trade receivables are as follows:

	2017	2016	2015
	(i	uS\$'000	)
As at January 1	110	165	285
Increase in provision for trade receivables	_	38	77
Decrease in provision due to subsequent collection	(41)	_	(185)
Transfer to assets classified as held for sale	_	(81)	_
Exchange differences	6	(12)	(12)
As at December 31	75	110	165

The impaired and provided receivables as at December 31, 2017 and December 31, 2016 were aged over 1 year.

# 12. Other Receivables, Prepayments and Deposits

	Decem	ber 31,	
	2017	2016	
	(in US	S\$'000)	
Prepayments to suppliers	3,272	850	
Value-added tax receivables	2,157	1,352	
Others	1,507	1,469	
	6,936	3,671	

## 13. Inventories

	Decem	ber 31,
	2017	2016
	(in US	\$*000)
Raw materials	14,853	10,326
Work in progress	14,808	9,537
Finished goods	_ 14,762	8,976
	44,423	28,839

Movements on the provision for excess and obsolete inventories are as follows:

	2017	2016	2015
	(i	n US\$'000)	
As at January 1	1,241	332	
Increase in provision for excess and obsolete inventories	529	972	340
Decrease in provision due to subsequent sale	(342)	_	
Write-off	(497)	_	
Exchange differences	69	(63)	(8)
As at December 31	1,000	1,241	332

#### 14. Assets Classified as Held For Sale

In December 2016, the board of directors and shareholders of Nanyang Baiyunshan Hutchison Whampoa Guanbao Pharmaceutical Company Limited ("NBHG") agreed in principle to a divestment of the Company's 60% majority interest in NBHG. As at December 31, 2016, the remaining step prior to the divestment was to complete the government-mandated auction process. Since the Company had held discussions with potential buyers, it had determined that a divestment was highly probable and accordingly, the Company reclassified the remaining assets and liabilities of NBHG as assets classified as held for sale and liabilities directly associated with assets classified as held for sale respectively.

The major classes of assets and liabilities associated with NBHG classified as net assets held for sale are as follows:

	December 31, 2016
	(in US\$'000)
Assets classified as held for sale:	
Cash and cash equivalents	134
Trade and bill receivables	12,360
Other receivables, prepayment and deposits	4,672
Inventories	6,949
Property, plant and equipment	241
Goodwill	172
Other intangible assets	546
Deferred tax assets	23
Total assets classified as held for sale	25,097
Liabilities directly associated with assets classified as held for sale:	
Trade payables	(9,400)
Other payables, accruals and advance receipts	(7,526)
Deferred tax liabilities	(136)
Total liabilities directly associated with assets classified as held for	
sale	(17,062)

On July 26, 2017, the Company received dividends of US\$1.6 million from NBHG and on September 1, 2017 completed the divestment of its majority interest in NBHG for consideration of US\$2.7 million (which was US\$2.6 million net of cash held at NBHG). Based on the then net assets associated with NBHG attributable to the Company of US\$2.9 million, the Company recorded a loss of \$0.2 million upon the divestment.

# 15. Property, Plant and Equipment

	Buildings and facilities	Plant and equipment	Furniture and fixtures, other equipment and motor vehicles  (in US\$'000)	Construction in progress	Total
Cost			(III C54 000)		
As at January 1, 2017	25,969	13,701	7,769	42,618	90,057
Additions	2,539	291	677	2,605	6,112
Disposals		(328)	(1,026)	, <u>—</u>	(1,354)
Transfers	32,214	11,847	580	(44,641)	_
Exchange differences	2,656	1,209	494	1,391	5,750
As at December 31, 2017	63,378	26,720	8,494	1,973	100,565
Accumulated depreciation					
As at January 1, 2017	8,550	10,088	6,289	_	24,927
Depreciation	1,762	1,841	777	_	4,380
Disposals	_	(484)	(704)	_	(1,188)
Exchange differences	568	665	396	_	1,629
As at December 31, 2017	10,880	12,110	6,758	_	29,748
Net book value					
As at December 31, 2017	52,498	14,610	1,736	1,973	70,817
	Buildi and		Furniture and fixtures, other equipment		
	facilit		ent vehicles	Construction in progress	Total
Cost				in progress	<u>Total</u>
Cost As at January 1, 2016		ies equipmo	ent vehicles (in US\$'000)	in progress	<b>Total</b> 78,698
	<u>facilit</u> 26,73	ies equipmo	vehicles (in US\$'000)  7,888	in progress	
As at January 1, 2016	26,7: 8	57 12,79 16 70	vehicles (in US\$'000)  7,888	31,259 15,390	78,698
As at January 1, 2016 Additions Disposals Transfers	26,7: 8	57 12,79 16 70	vehicles (in US\$'000)  7,888 (6 926 1) (53) 4 17	31,259 15,390	78,698 17,838 (89)
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale	26,7: 8 (1	57 12,79 16 70 25) (1 26 1,13	vehicles (in US\$'000)  7,888 66 926 1) (53) 64 17 - (447)	31,259 15,390 — (1,377)	78,698 17,838 (89) — (447)
As at January 1, 2016 Additions Disposals Transfers	26,7: 8	57 12,79 16 70 25) (1 26 1,13	vehicles (in US\$'000)  7,888 (6 926 (1) (53) (44 17 (447)	31,259 15,390 — (1,377)	78,698 17,838 (89)
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale	26,7: 8 (1	57 12,79 16 70 25) (1 26 1,13 05) (92	ent         vehicles           (in US\$'000)           04         7,888           06         926           11)         (53)           34         17            (447)           22)         (562)	31,259 15,390 — (1,377)	78,698 17,838 (89) — (447)
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences	26,7: 8 (1,8)	57 12,79 16 70 25) (1 26 1,13 05) (92	ent         vehicles           (in US\$'000)           04         7,888           06         926           11)         (53)           34         17            (447)           22)         (562)	31,259 15,390 — (1,377) — (2,654)	78,698 17,838 (89) — (447) (5,943)
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016	26,7: 8 (1,8)	57 12,79 16 70 25) (1 26 1,13 05) (92 69 13,70	ent         vehicles           (in US\$'000)           04         7,888           06         926           11         (53)           34         17            (447)           02         (562)           01         7,769	31,259 15,390 — (1,377) — (2,654)	78,698 17,838 (89) — (447) (5,943) 90,057
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016 Accumulated depreciation As at January 1, 2016 Depreciation	26,7: 8 (1,8) 25,9)	12,79 16 70 25) (1 26 1,13 05) (92 13,70 74 10,07 42 59	ent         vehicles           (in US\$'000)           94         7,888           96         926           1)         (53)           34         17           -         (447)           22)         (562)           91         7,769           70         6,163           92         793	31,259 15,390 — (1,377) — (2,654) 42,618	78,698 17,838 (89) — (447) (5,943) 90,057 24,007 2,227
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016 Accumulated depreciation As at January 1, 2016 Depreciation Disposals	26,7: 8 (1,8) 25,90 7,7' 8	12,79 16 70 25) (1 26 1,13 05) (92 69 13,70 74 10,07 42 59 (1) (1	ent         vehicles           (in US\$'000)           04         7,888           06         926           1)         (53)           64         17           —         (447)           (22)         (562)           01         7,769           70         6,163           72         793           (9)         (19)	31,259 15,390 — (1,377) — (2,654) 42,618	78,698 17,838 (89) — (447) (5,943) 90,057 24,007 2,227 (29)
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016 Accumulated depreciation As at January 1, 2016 Depreciation Disposals Impairment	26,7: 8 (1,8) 25,90 7,7' 8	12,79 16 70 25) (1 26 1,13 05) (92 13,70 74 10,07 42 59	ent         vehicles           (in US\$'000)           04         7,888           06         926           1)         (53)           34         17           -         (447)           (22)         (562)           01         7,769           70         6,163           02         793           (9)         (19)           60         -	31,259 15,390 — (1,377) — (2,654) 42,618	78,698 17,838 (89) — (447) (5,943) 90,057 24,007 2,227 (29) 617
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016 Accumulated depreciation As at January 1, 2016 Depreciation Disposals Impairment Transfer to assets classified as held for sale	26,7: 8 (( 22, (1,8) 25,9) 7,7' 8	12,79 16 70 25) (1 26 1,13 05) (92 69 13,70 74 10,07 42 59 (1) (87 13	ent         vehicles           (in US\$'000)           04         7,888           06         926           1)         (53)           64         17           -         (447)           (22)         (562)           01         7,769           70         6,163           72         793           79         (19)           60         -           -         (206)	31,259 15,390 — (1,377) — (2,654) 42,618	78,698 17,838 (89) — (447) (5,943) 90,057 24,007 2,227 (29) 617 (206)
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016 Accumulated depreciation As at January 1, 2016 Depreciation Disposals Impairment Transfer to assets classified as held for sale Exchange differences	26,7: 8 (( 22, (1,8) 25,9) 7,7' 8	12,79 16 70 25) (1 26 1,13 05) (92 69 13,70 74 10,07 42 59 (1) (1	ent         vehicles           (in US\$'000)           04         7,888           06         926           1)         (53)           64         17           -         (447)           (22)         (562)           01         7,769           70         6,163           72         793           (39)         (19)           60         -           -         (206)	31,259 15,390 — (1,377) — (2,654) 42,618	78,698 17,838 (89) — (447) (5,943) 90,057 24,007 2,227 (29) 617
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016 Accumulated depreciation As at January 1, 2016 Depreciation Disposals Impairment Transfer to assets classified as held for sale	26,7: 8 (( 22, (1,8) 25,9) 7,7' 8	ies         equipme           57         12,79           16         70           25)         (1           26         1,13           69         13,70           74         10,07           42         59           (1)         (6           87         13           52)         (69	ent         vehicles           (in US\$'000)           94         7,888           96         926           1)         (53)           34         17           -         (447)           22)         (562)           91         7,769           70         6,163           92         793           79         (19)           60         -           60         -           25         (442)	31,259 15,390 — (1,377) — (2,654) 42,618	78,698 17,838 (89) — (447) (5,943) 90,057 24,007 2,227 (29) 617 (206)
As at January 1, 2016 Additions Disposals Transfers Transfer to assets classified as held for sale Exchange differences As at December 31, 2016 Accumulated depreciation As at January 1, 2016 Depreciation Disposals Impairment Transfer to assets classified as held for sale Exchange differences	26,7: 8 (1,8) 25,9) 7,7' 8- (5.	ies         equipme           57         12,79           16         70           25)         (1           26         1,13           69         13,70           74         10,07           42         59           (1)         (6           87         13	ent         vehicles           (in US\$'000)           94         7,888           96         926           1)         (53)           34         17	31,259 15,390 — (1,377) — (2,654) 42,618	78,698 17,838 (89) — (447) (5,943) 90,057 24,007 2,227 (29) 617 (206) (1,689)

	Buildings and facilities	Plant and equipment	Furniture and fixtures, other equipment and motor vehicles	Construction in progress	Total
			(in US\$'000)		
Cost					
As at January 1, 2015	26,972	13,275	7,842	9,989	58,078
Additions	638	663	352	22,541	24,194
Disposals	(13)	(609)	(53)		(675)
Transfers	260	_	70	(330)	_
Exchange differences	(1,100)	(535)	(323)	(941)	(2,899)
As at December 31, 2015	26,757	12,794	7,888	31,259	78,698
Accumulated depreciation					
As at January 1, 2015	6,978	10,276	5,629	_	22,883
Depreciation	1,101	949	827		2,877
Disposals	_	(572)	(49)	_	(621)
Exchange differences	(305)	(583)	(244)		(1,132)
As at December 31, 2015	7,774	10,070	6,163		24,007
Net book value					
As at December 31, 2015	18,983	2,724	1,725	31,259	54,691

Construction in progress in 2015 and 2016 mainly related to the construction of a new office building and a new factory. In March 2017 and December 2017, the new factory and the new office became ready for its intended use respectively.

#### 16. Deferred Tax Assets and Liabilities

	Decem	December 31,	
	2017	2016	
	(in Us	S\$'000)	
Deferred tax assets	2,489	1,717	
Deferred tax liabilities	(114)	(131)	
Net deferred tax assets	2,375	1,586	

The movements in net deferred tax assets are as follows:

	2017	2016	2015
	(i	in US\$'000)	
At January 1	1,586	667	606
Credited/(debited) to the consolidated income statements			
—tax losses	657	552	354
—accrued expenses, provisions, depreciation allowances	12	335	(268)
Transfer to assets classified as held for sale (Note 14)	_	113	
Exchange differences	120	(81)	(25)
At December 31	2,375	1,586	667

The deferred tax assets and liabilities are offset when there is a legally enforceable right to set off and when the deferred income taxes related to the same fiscal authority.

The Group's deferred tax assets and liabilities are temporary differences including tax losses, accrued expenses, provisions and depreciation allowances. The potential deferred tax assets in respect of tax losses

which have not been recognized in the consolidated financial statements were approximately US\$612,000 (2016: US\$215,000).

These unrecognized tax losses can be carried forward against future taxable income and will expire in the following years:

	Decer	December 31,	
	2017	2016	
	(in U	(S\$'000)	
2018	170	160	
2019	207	195	
2020	240	345	
2021	169	159	
2022	1,661_	_	
	2,447	859	

#### 17. Other Non-Current Assets

	Decem	December 31,		
	2017	2016		
	(in US	(in US\$'000)		
Leasehold land rights (note (i))	11,160	10,504		
Restricted cash (note (ii))	206			
	11,366	10,504		

#### Notes:

- (i) Represents payments for a land use right. The title of the land is in the process of registration, pending remaining administrative procedures. The respective payments are recorded in other non-current assets until the registration is completed and title is transferred to the Company. As at December 31, 2017, this process is still in progress.
- (ii) Restricted cash is comprised of a deposit subject to a contractual restriction up to March 2019 and is therefore not available for general use by the Group.

## 18. Trade Payables

	Decemb	December 31,	
	2017	2016	
	(in US	\$'000)	
Trade payables—third parties	11,707	13,285	
Trade payables—related parties (Note 23(b))	3,838	5,290	
	15,545	18,575	

All the trade payables are denominated in RMB and due within one year from the end of the reporting period. The carrying value of trade payables approximates their fair values due to their short-term maturities.

# 19. Other Payables, Accruals and Advance Receipts

	December 31,	
	2017	2016
	(in US	\$'000)
Other payables and accruals		
Accrued salaries and benefits	5,512	5,072
Accrued selling and administrative expenses	4,920	9,464
Value-added tax and tax surcharge payables	2,178	2,257
Deposits received	2,894	2,455
Finance lease payables	104	93
Dividends payable	15,256	174
Other payables to manufacturers	4,323	1,766
Others	10,987	6,978
	46,174	28,259
Advance receipts		
Payments in advance from customers	11,423	3,499
Deferred government incentives (note)	1,418	1,931
	12,841	5,430
	59,015	33,689

Note: The deferred government incentives are related to the property, plant and equipment and research and development projects which are expected to be completed within one year.

# 20. Deferred Income

	Decer	December 31,	
	2017	2016	
	(in U	S\$'000)	
Deferred government incentives:			
Buildings and other non-current assets	13,850	13,462	
Others	4,398	4,104	
	18,248	17,566	

#### 21. Notes to the Consolidated Statements of Cash Flows

## (a) Reconciliation of profit for the year to net cash generated from operations:

	Year Ended December 31,		ber 31,
	2017	2016	2015
		in US\$'000)	
Profit for the year	20,805	20,128	21,216
Adjustments to reconcile profit for the year to net cash			
generated from operations			
Taxation charge	3,629	3,631	3,948
Finance costs	117	123	158
Interest income	(220)	(238)	(628)
Share of profits of joint venture and associated			
companies, net of tax	(65)	(19)	(6)
Depreciation on property, plant and equipment	4,380	2,227	2,877
Loss on disposal of property, plant and equipment	166	60	54
Impairment of property, plant and equipment	_	617	
Amortization of leasehold land	253	255	271
Amortization of other intangible assets	352	476	126
Movements on the provision for trade receivables	(41)	38	77
Movements on the provision for excess and obsolete			
inventories	187	972	340
Amortization of deferred income	(1,076)	(1,941)	(1,262)
Loss on divestment of a subsidiary	169	_	
Exchange differences	1,363	(810)	(710)
Changes in working capital:			
Trade and bills receivables	6,903	(15,266)	5,992
Other receivables, prepayments and deposits	(3,265)	(2,153)	(911)
Inventories	(15,771)	2,633	3,837
Other non-current assets	(206)	_	
Trade payables	(3,424)	10,531	(12,424)
Other payables, accruals and advance receipts	11,194	(4,838)	(10,677)
Movements on the net assets classified as held for			
sale	(606)	_	_
Total changes in working capital	(5,175)	(9,093)	(14,183)
Net cash generated from operations	24,844	16,426	12,278
•			

## (b) Supplemental disclosure for non-cash activities

During the year ended December 31, 2016, a non-controlling shareholder of a subsidiary made an additional capital contribution in the form of intangible assets amounting to US\$3.6 million.

During the year ended December 31, 2017, there was a decrease in accruals made for purchases of property, plant and equipment of US\$1.1 million. During the year ended December 31, 2016, there was an increase in accruals made for purchases of property, plant and equipment of US\$3.7 million.

## 22. Commitments

# (a) Capital commitments

The Group had the following capital commitments:

	Decen	December 31,	
	2017	2016	
	(in U	S\$'000)	
Property, plant and equipment			
Contracted but not provided for	460	6,162	

Capital commitments for property, plant and equipment are mainly for the construction in progress of a new office building and a manufacturing plant.

# (b) Operating lease commitments

The Group leases various factories and warehouses under non-cancellable operating lease agreements. The future aggregate minimum lease payments in respect of land and buildings under non-cancellable operating leases were as follows:

	D	December 31,	
	2017	,	2016
		(in US\$'000)	
Not later than 1 year	9	99	1,106
Between 1 to 2 years	3	79	1,080
Between 2 to 3 years	1	41	_
Between 3 to 4 years	1	41	_
Between 4 to 5 years		47	
	1,7	07	2,186

# 23. Significant Related Party Transactions

The Group has the following significant transactions during the years with related parties which were carried out in the normal course of business at terms determined and agreed by the relevant parties:

# (a) Transactions with related parties:

	Year Ended December 31,		
	2017	2016	2015
		(in US\$'000)	
Sales of goods to:			
—Fellow subsidiaries of GBPHCL	24,252	22,872	25,688
—A fellow subsidiary of GZHCMHK	946	280	152
	25,198	23,152	25,840
Other services income from:			
—Fellow subsidiaries of GBPHCL	3,171	2,310	875
Purchase of goods from:			
—An equity investee	1,726	745	198
—Fellow subsidiaries of GBPHCL	31,446	36,291	32,156
	33,172	37,036	32,354
Advertising expenses to:			
—A fellow subsidiary of GBPHCL	5,957	3,527	6,353
Interest paid to:			
—A fellow subsidiary of GBPHCL	92	85	122
—A non-controlling shareholder of a subsidiary	25		
	117	<u>85</u>	122

No transactions have been entered into with the directors of the Company (being the key management personnel) during the year ended December 31, 2017 (2016 and 2015: nil).

# (b) Balances with related parties included in:

	December 31,	
	2017	2016
	(in US	<b>\$'000</b> )
Trade receivable—related parties		
—Fellow subsidiaries of GZHCMHK (note (i))	20	_
—Fellow subsidiaries of GBPHCL (note (i))	265	466
	285	466
Trade payables—related parties		
—Fellow subsidiaries of GBPHCL (Note 18 and note (i))	3,838	5,290
Other receivables—related parties		
—Fellow subsidiaries of GBPHCL (note (i))	727	972
—An equity investee (note (i))	443	
	1,170_	972
Other payables, accruals and advance receipt—related parties		
—Fellow subsidiaries of GZHCMHK (note (i))	158	286
—Fellow subsidiaries of GBPHCL (note (i))	3,231	539
—GBPHCL (note (ii))	2,477	2,332
—GZHCMHK (dividend payable)	7,628	_
—GBPHCL (dividend payable)	7,628	_
—Non-controlling shareholder of NBHG (dividend payable)		174
	21,122	3,331

#### Notes:

- (i) Balances are unsecured, interest-free and repayable on demand. The carrying values of balances with related parties approximate their fair values due to their short-term maturities.
- (ii) Balance is unsecured, interest bearing and repayable on demand. The carrying value of balance with a related party approximates its fair value due to its short-term maturity.

# 24. Particulars of Principal Subsidiaries, Joint Venture and Associated Companies

		of reg	al value istered ital	Equity interest attributable to the Group			
	Place of establishment	As Decem	at ber 31,		at ber 31,		
Name	and operation	2017	2016	2017	2016	Type of legal entity	Principal activity
Hutchison Whampoa Guangzhou Baiyunshan Chinese Medicine (Bozhou) Co. Ltd	PRC	(in RM	100,000	100%	100%	Limited liability company	Manufacture, sales and distribution of drug products
Hutchison Whampoa Guangzhou Baiyunshan Pharmaceuticals Limited	PRC	10,000	10,000	100%	100%	Limited liability company	Sales and marketing of drug products
Hutchison Whampoa Guangzhou Baiyunshan Health & Wellness Co. Ltd	PRC	10,000	10,000	100%	100%	Limited liability company	Health supplemented food distribution
Hutchison Whampoa Baiyunshan Lai Da Pharmaceuticals (Shan Tou) Company Limited	PRC	10,000	10,000	70%	70%	Limited liability company	Manufacture, sales and distribution of drug products
Fuyang Baiyunshan Hutchison Whampoa Chinese Medicine Technology Company Limited	PRC	3,650	3,650	75%	75%	Limited liability company	Agriculture and sales of Chinese herbs
Wenshan Baiyunshan Hutchison Whampoa Qidan Sanqi Chinese Medicine Co. Ltd.	PRC	2,000	2,000	51%	51%	Limited liability company	Agriculture and sales of Chinese herbs
Daqing Baiyunshan Hutchison Whampoa Banlangen Technology Company Limited	PRC	1,020	1,020	51%	51%	Limited liability company	Agriculture and sales of Chinese herbs
Shen Nong Garden Traditional Chinese Medicine Museum	PRC	1,000	1,000	100%	100%	Non-profit making organization	Promote awareness of Chinese herbs
Nanyang Baiyunshan Hutchison Whampoa Danshen R&D Limited	PRC	1,000	1,000	51%	51%	Limited liability company	Agriculture and sales of Chinese herbs
Bozhou Baiyunshan Pharmaceuticals Co Ltd	PRC	500	500	100%	100%	Limited liability company	Manufacture, sales and distribution of drug products
NBHG	PRC	_	30,000	_	60%	Limited liability company	Sales of drug products
Joint Venture							
Qing Yuan Baiyunshan Hutchison Whampoa ChuanXinLian R&D Limited	PRC	1,000	1,000	50%	50%	Limited liability company	Agriculture and sales of Chinese herbs
Associated companies							
Linyi Shenghe Jiuzhou Pharmaceuticals Company Limited	PRC	3,000	3,000	30%	30%	Limited liability company	Agriculture and sales of Chinese herbs
Tibet Lizhi Guangzhou Pharmaceutical Development Co. Ltd.	PRC	2,000	2,000	20%	20%	Limited liability company	Trading of Chinese herbs

# 25. Subsequent events

The Group evaluated subsequent events through March 9, 2018, which is the date when the consolidated financial statements were issued.

NUTRITION SCIENCE PARTNERS LIMITED

#### **Report of Independent Auditors**

#### To the Board of Directors and Shareholders of Nutrition Science Partners Limited

We have audited the accompanying consolidated financial statements of Nutrition Science Partners Limited and its subsidiary, which comprise the consolidated statements of financial position as of December 31, 2017 and 2016, and the related consolidated income statements, consolidated statements of comprehensive income, of changes in equity and of cash flows for each of the three years in the period ended December 31, 2017.

# Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

# Auditors' Responsibility

Our responsibility is to express an opinion on the consolidated financial statements based on our audits. We conducted our audits in accordance with audit standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the Company's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

# **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Nutrition Science Partners Limited and its subsidiary as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017, in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

/s/ PricewaterhouseCoopers Hong Kong March 9, 2018

# Nutrition Science Partners Limited Consolidated Income Statements (in US\$'000)

			nded Decemb	er 31,
	Note	2017	2016	2015
Revenue		_	_	_
Service fees charged by related parties	5	(8,893)	(8,123)	(5,712)
Clinical trial expenses		<u> </u>	(40)	(427)
Other research and development costs		(242)	(281)	(1,371)
Other expenses		(75)	(38)	(42)
Loss before taxation		(9,210)	(8,482)	(7,552)
Taxation charge	6	_	_	_
Loss for the year		(9,210)	(8,482)	(7,552)

# Nutrition Science Partners Limited Consolidated Statements of Comprehensive Income (in US\$'000)

	Year E	Year Ended December 31,		
	2017	2016	2015	
Loss for the year	(9,210)	(8,482)	(7,552)	
Total comprehensive loss for the year	(9,210)	(8,482)	(7,552)	

# Nutrition Science Partners Limited Consolidated Statements of Financial Position (in US\$'000)

		Decemb	er 31,
	Note	2017	2016
Assets			
Current assets			
Cash and cash equivalents	7	9,640	5,393
Non-current assets			
Intangible asset	8	30,000	30,000
Total assets		39,640	35,393
Liabilities and shareholders' equity			
Current liabilities			
Other payables and accruals		289	140
Amounts due to related companies	10	950	1,642
Total liabilities		1,239	1,782
Shareholders' equity			
Share capital	9	98,000	84,000
Accumulated losses		(59,599)	(50,389)
Total shareholders' equity		38,401	33,611
Total liabilities and shareholders' equity		39,640	35,393

# Nutrition Science Partners Limited Consolidated Statements of Changes in Equity (in US\$'000)

	Share capital	Accumulated losses	Total equity
As at January 1, 2015	60,000	(34,355)	25,645
Total comprehensive loss		(7,552)	(7,552)
As at December 31, 2015	60,000	(41,907)	18,093
Issuance of share capital	10,000	_	10,000
Capitalization of shareholders' loans (Note 11)	14,000	_	14,000
Total comprehensive loss		(8,482)	(8,482)
As at December 31, 2016	84,000	(50,389)	33,611
Issuance of share capital	14,000	_	14,000
Total comprehensive loss		(9,210)	(9,210)
As at December 31, 2017	98,000	(59,599)	38,401

# Nutrition Science Partners Limited Consolidated Statements of Cash Flows (in US\$'000)

		Year Ended December		er 31,
	Note	2017	2016	2015
Operating activities				
Loss before taxation		(9,210)	(8,482)	(7,552)
Changes in working capital:				
Decrease in prepayments		_	410	1,889
Increase/(decrease) in other payables and accruals		149	(311)	(1,942)
(Decrease)/increase in amounts due to related companies		(692)	1,152	(20)
Net cash used in operating activities		(9,753)	(7,231)	(7,625)
Financing activities				
Proceeds from issuance of share capital	9	14,000	10,000	_
Proceeds from shareholders' loans	11			4,000
Net cash generated from financing activities		14,000	10,000	4,000
Net increase/(decrease) in cash and cash equivalents		4,247	2,769	(3,625)
Cash and cash equivalents				
Cash and cash equivalents at beginning of year		5,393	2,624	6,249
Cash and cash equivalents at end of year		9,640	5,393	2,624
Supplemental disclosure of non-cash activities				
Capitalization of shareholders' loans	11		14,000	

# Nutrition Science Partners Limited Notes to the Consolidated Financial Statements

#### 1. General Information

Nutrition Science Partners Limited (the "Company") and its subsidiary (together, the "Group") are principally engaged in the research and development of pharmaceutical products. The Company was incorporated in Hong Kong on May 28, 2012 as a limited liability company. The registered office of the Company is located at 22nd Floor, Hutchison House, 10 Harcourt Road, Hong Kong.

On November 27, 2012, Hutchison MediPharma (Hong Kong) Limited ("HMPHK"), a subsidiary of Hutchison China MediTech Limited ("Chi-Med", which together with its subsidiaries, hereinafter collectively referred to as the "Chi-Med Group") and Nestlé Health Science S.A. ("NHS"), a subsidiary of Nestlé S.A. ("Nestlé"), entered into a joint venture agreement ("JV Agreement"). Pursuant to the JV Agreement, Nestlé agreed to contribute cash of US\$30,000,000 and the Chi-Med Group agreed to contribute into the Company assets and business processes including (i) the global development and commercial rights of a novel, oral therapy drug candidate for Inflammatory Bowel Disease ("IBD") and (ii) the exclusive rights to its extensive botanical library and well-established botanical research and development platform in the field of gastrointestinal disease. The Company would be jointly owned by HMPHK and NHS having 50% equity interest each.

These consolidated financial statements are presented in United States dollars ("US\$"), unless otherwise stated and have been approved for issue by the Company's Board of Directors on March 9, 2018.

# 2. Summary of Significant Accounting Policies

The consolidated financial statements of the Company have been prepared in accordance with International Financial Reporting Standards ("IFRS") and interpretations issued by the IFRS Interpretations Committee applicable to companies reporting under IFRS. The consolidated financial statements comply with IFRS as issued by International Accounting Standards Board ("IASB"). These consolidated financial statements have been prepared under the historical cost convention.

As of December 31, 2017, the Company has accumulated losses of US\$59,599,000 (2016: US\$50,389,000) due to its research and development activities. The Company relies on HMPHK and NHS for financial support. In preparing these consolidated financial statements, management, including the directors of the Company, has taken into account all available information about the foreseeable future, which is at least, but is not limited to, twelve months from the end of the report issuance date. Management considers a wide range of factors relating to the availability and sufficiency of the Group's financial resources to satisfy its working capital and other financing requirements for a reasonable period of time, including, the progress and results of its new and in-progress research and development projects ("IPR&D projects"), the Group's current and expected future financial performance and operating cash flows, availability of loans and other financial support from shareholders, and potential sources of new funds. HMPHK and NHS have confirmed their intention to provide financial support to the Company to meet its liabilities as and when they fall due. Accordingly, the Directors are of the opinion that the Group will be able to meet its liabilities as and when they fall due within the next twelve months and therefore have prepared these consolidated financial statements on a going concern basis.

During the year, the Group has adopted all of the new and revised standards, amendments and interpretations issued by the IASB that are relevant to the Group's operations and mandatory for annual periods beginning January 1, 2017. The adoption of these new and revised standards, amendments and interpretations did not have any material effects on the Group's results of operations or financial position.

The following standards, amendments and interpretations were in issue but not yet effective for financial year ended December 31, 2017 and have not been early adopted by the Group:

IAS 28 (Amendments) <sup>(1)</sup>	Investments in Associates and Joint Ventures
IAS 40 (Amendments) <sup>(1)</sup>	Transfers of Investment Property
IFRS 2 (Amendments) <sup>(1)</sup>	Classification and Measurement of Share-based
	Payment Transactions
IFRS 9 <sup>(1)</sup>	Financial Instruments
IFRS 10 and IAS 28 (Amendments) <sup>(3)</sup>	Sale or Contribution of Assets between an Investor
	and its Associate or Joint Venture
IFRS 15 <sup>(1)</sup>	Revenue from Contracts with Customers
IFRS 15 (Amendments) <sup>(1)</sup>	Revenue from Contracts with Customers
IFRS 16 <sup>(2)</sup>	Leases
IFRIC 22 <sup>(1)</sup>	Foreign Currency Transactions and Advance
	Consideration
IFRIC 23 <sup>(2)</sup>	Uncertainty over Income Tax Treatments
Annual improvement 2014-2016 <sup>(1)</sup>	Improvements to IFRSs
Annual improvement 2015-2017 <sup>(2)</sup>	Improvements to IFRSs

- (1) Effective for the Group for annual periods beginning on or after January 1, 2018.
- (2) Effective for the Group for annual periods beginning on or after January 1, 2019.
- (3) No mandatory effective date determined yet, but available for adoption.

The adoption of standards, amendments and interpretations listed above in future periods is not expected to have any material effect on the Group's result of operations and financial position.

# (a) Basis of Consolidation

The consolidated financial statements of the Group include the financial statements of the Company and its subsidiary. The financial statements of the subsidiary are prepared for the same reporting period as the Company, using consistent accounting policies. The results of the subsidiary are consolidated from the date on which the Group obtained control, and will continue to be consolidated until the date that such control ceases. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

#### (b) Subsidiary

The subsidiary is an entity over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. In the consolidated financial statements, the subsidiary is accounted for as described in Note 2(a) above.

#### (c) Foreign Currency Translation

Items included in the financial statements of each of the Group's companies are measured using the currency of the primary economic environment in which the entity operates. The consolidated financial statements are presented in US\$, which is the Company's functional and presentation currency.

# (d) Segment Reporting

The Group has one operating segment which conducts research and development activities. All segment assets are located in Hong Kong. The Group's chief operating decision-makers review the consolidated results of the Group for the purposes of resource allocation and performance assessment. Therefore, no additional reportable segment and geographical information has been presented.

#### (e) Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least annually. The Group has no intangible assets with indefinite lives.

# (f) Research and Development Costs

All research costs are charged to the consolidated income statements as incurred.

Expenditures incurred on projects to develop new products are capitalized and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure the expenditure reliably during the development. Product development expenditures which do not meet these criteria are expensed when incurred.

# (g) Cash and Cash Equivalents

In the consolidated statements of cash flows, cash and cash equivalents comprise cash at bank.

#### (h) Provisions

Provisions are recognized when the Group has a present legal or constructive obligation as a result of past events; it is probable that an outflow of resources will be required to settle the obligation; and the amount has been reliably estimated. Provisions are not recognized for future operating losses.

#### (i) Income Tax

The current tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Company and its subsidiary operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and establish provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

#### 3. Financial Risk Management

#### (i) Financial Risk Factors

The Group's activities expose it to a variety of financial risks, including credit risk and liquidity risk. The Group does not use any derivative financial instruments for speculative purposes.

# (a) Credit Risk

The carrying amounts of cash and cash equivalents included in the consolidated statements of financial position represent the Group's maximum exposure to credit risk of the counterparty in relation to its financial asset. The Group's bank balance is maintained with a creditworthy bank with no recent history of default.

# (b) Liquidity Risk

The Group's objective is to maintain a balance between continuity of funding and flexibility through balances with related companies and shareholders.

As at December 31, 2017 and 2016, the Group's current financial liabilities were all contractually due for settlement within twelve months and expects to meet all liquidity requirements.

# (ii) Capital Management

The primary objective of the Group's capital management is to safeguard the Group's ability to continue as a going concern.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made to these objectives, policies or processes for managing capital during the years ended December 31, 2017, 2016 and 2015.

#### (iii) Fair Value Estimation

The fair values of the financial asset and liabilities of the Group approximate their carrying amounts largely due to the short term maturities of these instruments.

# 4. Critical Accounting Estimates and Judgements

Note 2 includes a summary of the significant accounting policies used in the preparation of the consolidated financial statements. The preparation of the consolidated financial statements often requires the use of judgements to select specific accounting methods and policies from several acceptable alternatives. Furthermore, significant estimates and assumptions concerning the future may be required in selecting and applying those methods and policies in the financial statements. The Group bases its estimates and judgements on historical experience and various other assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates and judgements under different assumptions or conditions.

The following is a review of the more significant assumptions and estimates, as well as the accounting policies and methods used in the preparation of the financial statements.

# (i) Impairment of intangible asset

The Group tests annually whether an intangible asset not ready for use has incurred any impairment. Assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets exceeds its recoverable amount in accordance with the accounting policy stated in Note 2(e). The recoverable amount of an asset or a cash-generating unit is determined based on the higher of the asset's or the cash-generating unit's fair value less costs to sell and value-in-use. The value-in-use calculation requires the entity to estimate the future cash flows expected to arise from the asset and a suitable discount rate in order to calculate present value, and the growth rate assumptions in the cash flow projections which have been prepared on the basis of management's assumptions and estimates.

The Group has adopted an income approach to determine the value-in-use of the intangible asset, which applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, probability of success rate, expected timing of commercialization and industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. Key assumptions and sensitivities are disclosed in Note 8.

# 5. Significant Related Party Transactions

(i) The Group has the following significant transactions during the years with related parties which were carried out in the normal course of business at terms equivalent to those that prevail in arm's length transactions and agreed by the relevant parties:

	Year Ended December 31,		ber 31,
	2017	2016	2015
		(in US\$'000)	)
Service fees charged by a subsidiary of Chi-Med	8,893	8,123	5,099
Service fees charged by an affiliate of NHS			613
	8,893	8,123	5,712

On March 25, 2013, Hutchison MediPharma Limited ("HMP"), a subsidiary of Chi-Med, and NHS entered into a research and development collaboration agreement as contemplated by the JV Agreement for the exclusive rights to conduct research to evaluate and develop products from HMP's extensive botanical library and well established botanical research and development platform in the field of gastrointestinal disease. The collaboration agreement will end on December 31, 2022, until which time the Company is required to spend a minimum of US\$500,000 in each calendar year on research activities.

The Company will own the right to any products arising from the future research and development. HMP and NHS will provide the necessary services and employees in order to provide the Company with the on-going research activities. HMP and NHS will be remunerated by a fee paid by the Company for the services and staff provided.

# (ii) Other transaction with related party:

On March 25, 2013, the Company and Nestec Ltd., an affiliate of NHS, entered into an option agreement for the exclusive option to obtain exclusive royalty-bearing licenses to commercialize certain products in certain territories. The exercise price of the option is either fixed or subject to negotiation upon the receipt of the exercise notice, depending on the territories. The value of the option is considered as negligible on day one. Because the option is not a derivative, it would not be subject to fair value remeasurement in the subsequent periods. As of December 31, 2017, the option has not been exercised.

# (iii) Compensation of key management personnel of the Group:

No compensation was paid by the Group to the key management personnel of the Group in respect of their services rendered to the Group during the years ended December 31, 2017, 2016 and 2015.

# 6. Taxation Charge

No Hong Kong profits tax has been provided as the Group had no assessable profit for the years ended December 31, 2017, 2016 and 2015.

The taxation on the Group's loss before taxation differs from the theoretical account that would arise using the applicable tax rate as follows:

	Year E	Year Ended December 31,		
	2017	2016	2015	
		(in US\$'000)		
Loss before taxation	(9,210)	(8,482)	(7,552)	
Calculated at a taxation rate of 16.5%	(1,520)	(1,400)	(1,246)	
Tax effect of expenses not deductible for tax				
purposes	1,520	1,400	1,246	
Taxation				

# 7. Cash and Cash Equivalents

	Decem	ber 31,
	2017	2016
	(in US	\$\$'000)
Cash at bank	9,640	5,393

The carrying amounts of the cash and cash equivalents are denominated in US\$.

# 8. Intangible Asset

	Decem	ber 31,
	2017	2016
	(in US	\$*7000)
IPR&D projects and others	30,000	30,000

# Impairment test for intangible asset

The recoverable amount of the intangible asset is determined based on a value-in-use calculation. The calculation uses cash flow projections based on projected revenues and estimated costs. The projections are based on factors such as projected market size and market share, probability of success rate, timing of commercialization and estimated useful life of the underlying assets. In 2017, the Chi-Med Group and NHS updated the development plan for the Company's drug candidate for IBD, which is an enhanced version of the drug with higher potential efficacy. The development plan was expanded to include more trials and increased numbers of patients, which was primarily due to the Company's strategy to strengthen the clinical data to support a future regulatory approval application.

The corresponding increase in investment reflects the Group's increased projected market size, which has been updated for a significant increase in patients in the past few years and the expected increase through the date of commercialization. In addition, the Group believes the potential market size includes all patients in the IBD market given the higher potential efficacy; therefore, the 2017 value-in-use calculation has been updated to include patients treated with biologic therapies, compared to the 2016 value-in-use calculation which excluded such patients. The Company expects global commercialization to occur in 2026. The discount rate used of 21.60% (2016: 20.37%) is derived from a capital asset pricing model using data from the markets. The budgeted revenues and costs are determined by management based on the most recent development plan of the project and its expectation of market development. Reasonably probable changes in any key assumptions disclosed in the sensitivity table would not cause the carrying amount of the intangible asset to exceed the recoverable amount.

The key assumptions used in the value-in-use calculation are as follows:

Key assumptions	2017	2016
Projected market size	US\$21 billion	US\$10 billion
Projected market share	10% of projected market size	10% of projected market size
Probability of success rate (Phase III)	61%	61%
Period of projected cash flows	23 years	24 years
Headroom	US\$22 million	US\$9 million

The Company prepared the financial projections taking into account actual and prior year performance and market development expectations. Judgement is required to determine key assumptions adopted in the cash flow projections.

The sensitivity of the value-in-use of the intangible asset to the changes in key assumptions is:

	Impact on the value-in-use of the intangible asset						
	Change in	Increase in	assumption	Decrease in assumption			
	assumption			2017	2016		
		Increase	Increase	Decrease	Decrease		
Market size	5%	by 14%	by 13%	by 14%	by 12%		
		Increase	Increase	Decrease	Decrease		
Probability of success rate	2% point	by 15%	by 13%	by 12%	by 14%		
		Decrease	Decrease	Increase	Increase		
Discount rate	1% point	by 22%	by 16%	by 25%	by 18%		

# 9. Share Capital

	2	017	2	016	2015	
	Number of shares	(in US\$'000)	Number of shares	(in US\$'000)	Number of shares	(in US\$'000)
Issued and fully paid:						
Ordinary shares						
At January 1	42,000	84,000	20,000	60,000	20,000	60,000
Issuance of shares (notes (i),						
note (ii))	7,000	14,000	20,000	10,000		_
Capitalization of shareholders' loans						
(Note 11)			2,000	14,000		
At December 31	49,000	98,000	42,000	84,000	20,000	60,000
Share capital as at December 31		98,000		84,000		60,000

#### Notes:

- (i) On February 22, 2017, 7,000 additional ordinary shares of US\$2,000 each were issued at a total cash consideration of US\$14,000,000. They are issued equally to the two existing shareholders.
- (ii) On March 30, 2016, 20,000 additional ordinary shares of US\$500 each were issued at a total cash consideration of US\$10,000,000. They are issued equally to the two existing shareholders.

#### 10. Amounts Due to Related Companies

Decemb	December 31,		
2017	2016		
(in US	(in US\$'000)		
950	1,642		
	2017 (in US		

The amounts due to related companies are unsecured, interest free and repayable on demand.

#### 11. Shareholders' Loans

Previously outstanding shareholders' loans of US\$5,000,000 each, totaling US\$10,000,000 were unsecured, interest-bearing (with immediate waiver of interest) and with an original maturity date of June 9, 2015, which is subject to extension from time to time by written consent from shareholders at the request of the Company. The loan agreement was renewed on August 24, 2015, with an effective date of June 9, 2015, and the maturity date extended to June 9, 2016.

On August 24, 2015, the shareholders have provided a further loan of US\$2,000,000 each, totaling US\$4,000,000. The loans are unsecured, interest-bearing (with immediate waiver of interest) and with a maturity date of August 23, 2016, which is subject to extension from time to time by written consent from shareholders at the request of the Company.

In June 2016, shareholders' loans of US\$14,000,000 in aggregate were waived and capitalized as share capital of the Company. No shareholders' loans were outstanding as at December 31, 2017 and 2016.

# 12. Directors' Emoluments

None of the directors received any fees or emoluments from the Group in respect of their services rendered to the Group during the years ended December 31, 2017, 2016 and 2015.

# 13. Subsidiary

Di 6		of issued ordinary share capital in GBP		Equity interest attributable to the Group			
	Place of establishment and	As at December 31, December 31,		Type of			
Name	operation	2017	2016	2017	2016	legal entity	Principal activity
Nutrition Science Partners						Limited liability	
(UK) Limited	United Kingdom	1	1	100%	100%	company	Inactive

Naminal valua

# 14. Subsequent Events

The Group evaluated subsequent events through March 9, 2018, which is the date when the consolidated financial statements were issued.