

13 February 2018

Outperform
Unchanged

重磅首仿获批上市

CSPC PHARMACEUTICAL GROUP (1093:HK)

Market Data: February, 12

Closing Price (HK\$)	16.64
Price Target (HK\$)	19.50
HSCEI	11,900
HSCCI	4,305
52-week High/Low (HK\$)	18.70/8.90
Market Cap (US\$m)	13,287
Market Cap (HK\$m)	103,884
Shares Outstanding (m)	6,243
Exchange Rate (Rmb-HK\$)	1.24

Price Performance Chart:



Source: Bloomberg

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Related Reports

"Strong pipeline-CSPC Pharmaceutical Group (1093:HK)" February 2, 2018

"Antibody acquisition-CSPC Pharmaceutical Group (1093:HK)" January 11, 2018

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Financial summary and valuation

	2015	2016	2017E	2018E	2019E
Revenue (HK\$ m)	11,393.73	12,369.04	15,066.55	17,749.45	20,858.82
YoY (%)	4.00	8.56	21.81	17.81	17.52
Net income (HK\$ m)	1,665.27	2,100.85	2,745.30	3,463.93	4,458.72
YoY (%)	31.28	26.16	30.68	26.18	28.72
EPS (HK\$)	0.28	0.35	0.44	0.55	0.71
Diluted EPS (HK\$)	0.28	0.35	0.44	0.55	0.71
ROE (%)	19.80	22.30	22.55	22.55	24.86
Debt/asset (%)	34.91	30.95	23.06	20.90	18.92
Dividend Yield (%)	0.66	0.72	0.92	1.17	1.50
PE (x)	59.04	47.21	37.84	29.99	23.30
PB (x)	11.16	9.73	7.25	6.26	5.32
EV/Ebitda (x)	35.68	30.55	24.10	19.67	15.71

Note: Diluted EPS is calculated as if all outstanding convertible securities, such as convertible preferred shares, convertible debentures, stock options and warrants, were exercised.

2月12日，公司宣布注射用紫杉醇（白蛋白结合型）获得CFDA的上市批准，用于治疗乳腺癌，成为国内首仿产品。我们预计该产品或将于今年3月初上市销售，并且有望于2024年达到16亿元峰值销售额。

重磅首仿品种。2016年，原研产品凯素（白蛋白结合型紫杉醇）的全球销售额为9.73亿美元。我们预计2017年凯素在中国市场的销售额约为3.5亿元。目前，CFDA已批准凯素用于治疗联合化疗失败的转移性乳腺癌或辅助化疗后6个月内复发的乳腺癌。此外，美国FDA还批准凯素用于治疗局部晚期或转移性非小细胞肺癌，并且与卡铂联用，作为不适合进行根治性手术或放疗的非小细胞肺癌患者的一线用药，以及与吉西他滨联用一线治疗转移性胰腺癌。另外，日本厚生劳动省已批准凯素用于治疗转移性胃癌。我们认为，在中国市场，凯素及其仿制品或将超适应症用于治疗非小细胞肺癌、胰腺癌以及胃癌。

渗透率有望大幅提升。国内主要有4类紫杉醇产品，即传统剂型紫杉醇、多西他赛、紫杉醇脂质体、以及白蛋白结合型紫杉醇。与其他类别的紫杉醇相比，白蛋白结合型紫杉醇发生严重过敏反应的概率较低，而其他类别的紫杉醇产品在使用前需要进行预处理，以防止严重过敏反应。2012年以来，凯素持续抢占传统剂型紫杉醇的市场份额。按照样本医院销售额口径，凯素在紫杉醇类市场的份额从2012年的0%提升至2017年前三季度的7%。按照销量口径，2017年前三季度，凯素的市场份额仅为1%，而紫杉醇脂质体的市场份额为20%。凯素的治疗费用较高，约为23,000元/疗程，紫杉醇脂质体的费用约7,300元/疗程。目前，凯素仅被纳入湖北和宁夏的省医保目录。我们估计，公司的白蛋白结合型紫杉醇定价约为2,500元/100毫克，比凯素的全国最低中标价低53%。由于公司的仿制药价格较低，大幅提升了该产品的可及性，将带来其渗透率的快速提升。

预期16亿元峰值销售额。《2015年中国癌症数据统计报告》显示，2015年中国新增乳腺癌患者约27.2万人，肺癌患者约73.3万人，胰腺癌患者约9.0万人，以及胃癌患者约67.9万人。我们认为，随着药品价格的持续降低，未来白蛋白结合型紫杉醇在晚期乳腺癌患者的渗透率有望提升至15%，在晚期非小细胞肺癌患者的渗透率或将达到12%，在转移性胰腺癌以及转移性胃癌患者的渗透率分别达到20%和5%。假设公司由于首仿优势，将抢占国内白蛋白结合型紫杉醇市场30%的份额，公司的产品有望于2024年达到16亿元峰值销售额。目前，另外4家国内厂商已向CFDA提交白蛋白结合型紫杉醇的仿制药上市申请，包括恒瑞医药（600276.CH-买入）、齐鲁制药、扬子江药业以及康禾生物制药。恒瑞医药的白蛋白结合型紫杉醇处于现场检查阶段，或将于18年上半年获得上市批准。

维持增持评级。我们维持17年稀释每股盈利为0.44港币（同比增长26%），18年稀释每股盈利为0.55港币（同比增长25%），19年稀释每股盈利为0.71港币（同比增长29%）。我们维持目标价19.50港币，对应35倍18年市盈率和27倍19年市盈率。目标价对应17%的上涨空间，我们维持增持评级。

Investment Highlights:

CSPC obtained China Food and Drug Administration (CFDA) approval for its albumin-bound form of paclitaxel injection for the treatment of breast cancer, becoming a first-to-market generic in China. We expect the product to be available in the market from beginning of March and its peak sales may reach c.Rmb1.6bn by 2024E. We maintain our diluted EPS forecasts of HK\$0.44 in 17E (+26% YoY), HK\$0.55 in 18E (+25% YoY) and HK\$0.71 in 19E (+29% YoY). We maintain our target price of HK\$19.50, and our Outperform rating.

First-to-market blockbuster. Global sales of the original drug, *Abraxane*, in 2016 hit US\$973m; we estimate *Abraxane's* sales in China at Rmb350m in 2017. *Abraxane* was approved by the CFDA for the treatment of metastatic breast cancer after failure of combination chemotherapy or relapsed breast cancer within six months of adjuvant chemotherapy. The US FDA also approved *Abraxane* for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment in combination with carboplatin, in NSCLC patients who are not candidates for curative surgery or radiation therapy, and combined with gemcitabine as a first-line treatment for metastatic adenocarcinoma of the pancreas. In addition, Japan's Ministry of Health, Labour and Welfare also approved *Abraxane* for the treatment of metastatic gastric cancer. We think, in China, *Abraxane* and its generic will be used off-label for treatment of NSCLC, pancreatic cancer and gastric cancer.

Higher penetration. *Abraxane* is superior to other forms of paclitaxel products due to much lower incidence of hypersensitivity reactions. *Abraxane* has gained market share from conventional paclitaxel products since 2012, with market share by revenue in sample hospitals rising from 0% in 2012 to 7% in 9M17. In terms of sales volume in sample hospitals, *Abraxane* had just a c.1% market share in 9M17 vs 20% for paclitaxel liposome. However, treatment cost for *Abraxane* is relatively expensive (c.Rmb23,000 per treatment cycle vs c.Rmb7,300 per treatment cycle for paclitaxel liposome). To date, *Abraxane* only enjoys reimbursement coverage in Hubei and Ningxia provinces. We expect CSPC's albumin-bound paclitaxel to be priced at c.Rmb2,500 per 100 mg, c.53% below *Abraxane's* lowest tender price of Rmb5,300 per 100 mg. As CSPC's *Abraxane* generic is much more affordable, we expect its penetration rate among oncology patients will increase rapidly.

Expect Rmb1.6bn peak sales. Assuming CSPC takes a 30% market share in the Chinese albumin-bound paclitaxel market, we expect peak sales of CSPC's albumin-bound paclitaxel to reach c.Rmb1.6bn by 2024E. Another four domestic players have filed abbreviated new drug applications (ANDAs) to the CFDA, namely Jiangsu Hengrui Medicine (600276:CH – BUY), Qilu Pharma, Yangtze River Pharma, and Jiangsu Kanghe Biologics. Jiangsu Hengrui Medicine's *Abraxane* generic is under CFDA on-site inspection and may also be approved in 1H18E.

Maintain Outperform. We maintain our diluted EPS forecasts of HK\$0.44 in 17E (+26% YoY), HK\$0.55 in 18E (+25% YoY) and HK\$0.71 in 19E (+29% YoY). We maintain our target price of HK\$19.50 (35x 18E PE and 27x 19E PE). With 17% upside, we maintain Outperform rating.

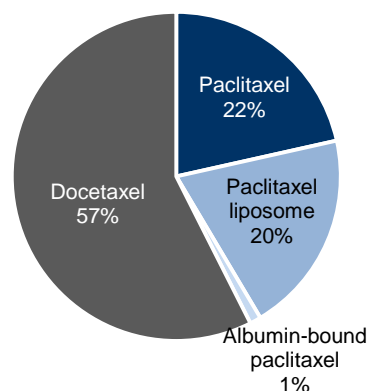
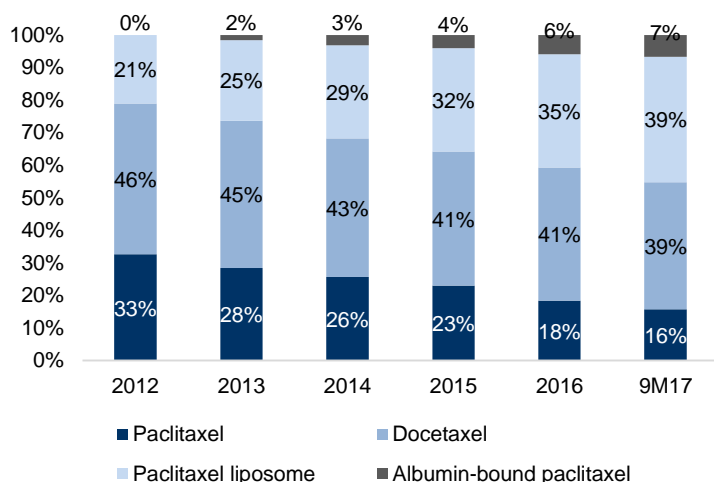
Fig 1: Comparison of paclitaxel products in China

Generic name	Brand name	Manufacturer	Status	Year of CFDA approval	Indication	Average tender price (Rmb per dose)	Cost per treatment cycle	Reimbursement coverage	Comments		
Paclitaxel	Taxol	BMS	Original drug	2002	Ovarian cancer, breast cancer, NSCLC	Rmb839 per 30mg	Rmb7,551	NRDL Type 1	Complicated premedication due to high incidence of hypersensitivity reactions, other side effects such as peripheral neuropathy, arthralgias, myalgias and neutropenia, prepared and infused using non-PVC infusion consumables, 3 hour infusion		
	Fuwang	Yangtze River Pharma	Generic	2005		Rmb176 per 30mg	Rmb1,584				
Docetaxel	Taxotere	Sanofi	Original drug	1998		Breast cancer, NSCLC	Rmb1,445 per 20mg	Rmb8,670		NRDL Type 2	Premedication needed 12 hours before administration due to high incidence of hypersensitivity reactions, 1 hour infusion
	Aisu	Jiangsu Hengrui	Generic	2002			Rmb364 per 20mg	Rmb2,184			
Paclitaxel liposome	Lipusu	Luye Pharma	Patent drug	2003	Ovarian cancer, breast cancer, NSCLC	Rmb916 per 30mg	Rmb7,328	26 PRDLs	Simple premedication, low incidence of hypersensitivity reactions, selective accumulation in tumors, long duration, 3 hour infusion		
Albumin-bound paclitaxel	Abraxane	Celgene	Original drug	2009	Breast cancer	Rmb5,739 per 100mg	Rmb22,956	2 PRDLs (limited to metastatic or relapsed breast cancer)	No premedication needed, selective accumulation in tumors, 30 minutes infusion		
	NA	CSPC	First-to-market generic	2018		Rmb2,500 per 100mg	Rmb10,000				

Source: Yaozh, Pharma Database, SWS Research

Fig 2: Market share by revenue of paclitaxel products (2012-9M17)

Fig 3: Market share by volume of paclitaxel products (9M17)



Source: Pharma Database, SWS Research

Source: Pharma Database, SWS Research

Fig 4: Sales projection for CSPC's albumin-bound paclitaxel

	2018E	2019E	2020E	2021E	2022E	2023E	2024E
Incidence of breast cancer in China (ppl)	272,400	280,572	288,989	297,659	306,589	315,786	325,260
Metastatic or relapsed breast cancer as % of total breast cancer	35.00%	35.00%	35.00%	35.00%	35.00%	35.00%	35.00%
Penetration rate of albumin-bound paclitaxel among metastatic or relapsed breast cancer patients	3.00%	6.00%	11.00%	13.00%	14.00%	14.50%	15.00%
Incidence of lung cancer in China (ppl)	730,000	751,900	774,457	797,691	821,621	846,270	871,658
NSCLC as % of total lung cancer	85.00%	85.00%	85.00%	85.00%	85.00%	85.00%	85.00%
Stage III & IV patients as % of total NSCLC	70.00%	70.00%	70.00%	70.00%	70.00%	70.00%	70.00%
Penetration rate of albumin-bound paclitaxel among stage III & IV NSCLC patients	2.00%	5.00%	8.00%	10.00%	11.00%	11.50%	12.00%
Incidence of pancreas cancer in China (ppl)	90,100	90,100	90,100	90,100	90,100	90,100	90,100
Metastatic pancreas cancer as % of total pancreas cancer	85.00%	85.00%	85.00%	85.00%	85.00%	85.00%	85.00%
Penetration rate of albumin-bound paclitaxel among metastatic pancreas cancer patients	5.00%	8.00%	12.00%	15.00%	18.00%	19.00%	20.00%
Incidence of gastric cancer in China (ppl)	679,100	679,100	679,100	679,100	679,100	679,100	679,100
Metastatic gastric cancer as % of total gastric cancer	90.00%	90.00%	90.00%	90.00%	90.00%	90.00%	90.00%
Penetration rate of albumin-bound paclitaxel among metastatic gastric patients	0.50%	1.00%	2.00%	3.00%	4.00%	4.50%	5.00%
Number of patients receiving albumin-bound paclitaxel (ppl)	18,432	40,500	69,404	90,830	107,031	115,987	125,189
Yearly treatment cost of receiving albumin-bound paclitaxel (Rmb)	60,000	58,200	56,454	54,760	53,118	51,524	49,978
CSPC's market share in Chinese albumin-bound paclitaxel market	20.00%	23.0%	26.00%	27.00%	28.00%	29.00%	30.00%
Annual net sales of albumin-bound paclitaxel (Rmbm)	189	463	871	1,148	1,361	1,481	1,604

Source: Company data, SWS Research

APPENDIX

Consolidated Income Statement					
(HK\$m)	2015	2016	2017E	2018E	2019E
Revenue	11,394	12,369	15,067	17,749	20,859
Cost of Sales	(6,173)	(6,060)	(6,144)	(6,745)	(7,509)
Gross Profit	5,221	6,309	8,922	11,005	13,350
Other Income	87	107	100	118	138
Selling/General/Admin. Expenses	(2,802)	(3,342)	(4,705)	(5,485)	(6,383)
EBITDA	2,772	3,237	4,102	5,028	6,296
EBIT	2,166	2,649	3,490	4,395	5,645
Finance Costs	(56)	(42)	(36)	(29)	(22)
Profit before tax	2,112	2,635	3,464	4,376	5,633
Income tax expense	(432)	(522)	(706)	(897)	(1,155)
Minority interests	(14)	(12)	(12)	(15)	(19)
Profit for the year	1,665	2,101	2,745	3,464	4,459

Source: Company data, SWS Research

Consolidated Cash Flow Statement					
(HK\$m)	2015	2016	2017E	2018E	2019E
Profit before taxation	2,112	2,635	3,464	4,376	5,633
Plus : Depr. and amortisation	605	588	613	633	651
Finance cost	56	42	36	29	22
Losses from investments	0	0	0	0	0
Change in working capital	(46)	219	(955)	(575)	(673)
Others	(478)	(567)	(743)	(926)	(1,177)
CF from operating activities	2,249	2,916	2,415	3,536	4,455
CAPEX	(758)	(1,090)	(800)	(800)	(800)
Other CF from investing activities	35	(242)	0	0	0
CF from investing activities	(723)	(1,332)	(800)	(800)	(800)
Equity financing	0	0	2,345	0	0
Net change in liabilities	263	(283)	(200)	(200)	(200)
Dividend and interest paid	(591)	(650)	(961)	(1,212)	(1,561)
Other CF from financing activities	(265)	481	0	0	0
CF from financing activities	(592)	(452)	1,184	(1,412)	(1,761)
Net cash flow	934	1,132	2,799	1,324	1,895
FCFF	1,535	1,844	1,641	2,756	3,668
FCFE	1,742	1,519	1,405	2,526	3,445

Source: Company data, SWS Research

Consolidated Balance Sheet					
(HK\$m)	2015	2016	2017E	2018E	2019E
Current Assets	7,648	8,428	12,109	14,298	17,236
Bank balances and cash	2,299	3,235	6,034	7,357	9,252
Trade and other receivables	1,878	1,835	2,477	2,918	3,429
Inventories	1,819	1,933	1,936	2,088	2,304
Other current assets	1,651	1,425	1,663	1,935	2,250
Long-term investment	28	172	172	172	172
PP&E	5,143	5,415	5,638	5,840	6,021
Intangible and other assets	722	746	710	676	644
Total Assets	13,540	14,760	18,629	20,986	24,072
Current Liabilities	3,484	4,085	3,812	3,902	4,071
Borrowings	452	898	698	498	298
Trade and other payables	2,489	2,938	2,862	3,141	3,497
Other current liabilities	544	249	253	263	276
Long-term liabilities	1,243	484	484	484	484
Total Liabilities	4,727	4,569	4,296	4,386	4,555
Minority Interests	75	84	96	111	130
Shareholder Equity	8,738	10,108	14,237	16,489	19,387
Share Capital	9,835	10,570	12,915	12,915	12,915
Reserves	(1,097)	(462)	1,322	3,574	6,472
Total Equity	8,813	10,191	14,333	16,599	19,517
Total Liabilities and equity	13,540	14,760	18,629	20,986	24,072

Source: Company data, SWS Research

Key Financial Ratios					
	2015	2016	2017E	2018E	2019E
Ratios per share (HK\$)					
Earnings per share	0.28	0.35	0.44	0.55	0.71
Diluted EPS	0.28	0.35	0.44	0.55	0.71
Operating CF per share	0.38	0.49	0.39	0.57	0.71
Dividend per share	0.11	0.12	0.15	0.19	0.25
Net assets per share	1.49	1.71	2.30	2.66	3.13
Key Operating Ratios(%)					
ROIC	15.81	17.54	17.14	19.01	21.11
ROE	19.80	22.30	22.55	22.55	24.86
Gross profit margin	45.82	51.00	59.22	62.00	64.00
EBITDA Margin	24.33	26.17	27.23	28.33	30.18
EBIT Margin	19.01	21.42	23.16	24.76	27.06
Growth rate of Revenue(YoY)	4.00	8.56	21.81	17.81	17.52
Growth rate of Profit(YoY)	31.28	26.16	30.68	26.18	28.72
Debt-to-asset ratio	34.91	30.95	23.06	20.90	18.92
Turnover rate of net assets	1.29	1.21	1.05	1.07	1.07
Turnover rate of total assets	0.84	0.84	0.81	0.85	0.87
Effective tax rate (%)	20.49	20.02	20.45	20.55	20.54
Dividend yield (%)	0.66	0.72	0.92	1.17	1.50
Valuation Ratios (X)					
P/E	59.04	47.21	37.84	29.99	23.30
P/B	11.16	9.73	7.25	6.26	5.32
EV/Sale	8.68	7.99	6.56	5.57	4.74

Source: Company data, SWS Research

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BUY: Share price performance is expected to generate more than 20% upside over a 12-month period.

Outperform: Share price performance is expected to generate between 10-20% upside over a 12-month period.

Hold: Share price performance is expected to generate between 10% downside to 10% upside over a 12-month period.

Underperform: Share price performance is expected to generate between 10-20% downside over a 12-month period.

SELL: Share price performance is expected to generate more than 20% downside over a 12-month period.

Industry Investment Rating:

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