

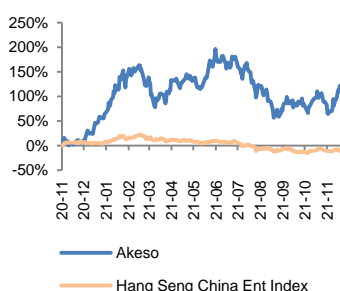
Pharmaceuticals |  
Company Research  
22 November 2021

## BUY Unchanged

### Market Data: 19 November 2021

Closing price (HK\$)	50.85
HSCEI	8,971
52-week high/Low (HK\$)	69.90/23.50
Market Cap (HK\$m)	41,547
Shares outstanding (m)	817
Exchange Rate (Rmb-HK\$)	0.9

### Price Performance Chart:



Source: Bloomberg

### Analyst

Zhou Wenyuan  
A0230518110003  
zhouwy@swsresearch.com

## R&D updates

### Akeso biotech (09926:HK)

Akeso recently announced three clinical trials results on AK104 (cadonilimab, PD-1/CTLA-4 bi-specific antibody) and AK112 (PD-1/VEGF bi-specific antibody), and three mechanism studies results on AK104, AK117 (CD47) and AK119 (CD73) at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021). We maintain our EPS forecasts of -Rmb0.85 in 21E, -Rmb0.77 in 22E and Rmb0.06 in 23E. We raise our target price from HK\$55.0 to HK\$62.0. With 22% upside, we maintain our BUY rating.

**AK112, Akeso's core bispecific product.** AK112 is a potential first-in-class PD-1/VEGF bispecific antibody. The drug now is under several phase Ib/II trials in China, including lung cancer, gynecological tumors, HCC, etc. On 15th November, Akeso announced two clinical results on AK112 in SITC 2021, including a phase I study in patients with platinum-resistant epithelial ovarian cancer (PROC) and a phase Ib/II clinical study of AK112 in combination with olaparib for patients with BRCA germline wild-type platinum sensitive recurrent ovarian cancer. In terms of AK112's phase I study on PROC, the ORR and DCR was 29.4% and 76.5% respectively. The median follow-up was 4.5 months and the rate of grade 3 or above treatment related adverse events (TRAEs) was 15.8%, with no grade 4-5 TRAEs. In addition, its phase Ib/II clinical study of AK112 combined with olaparib (PARP inhibitor), will evaluate the three dose levels of AK112 (10mg/kg, 20mg/kg and 30mg/kg Q2W) combined with fixed-dose olaparib (300mg, BID) to determine the recommended Phase II dose (RP2D). In addition, the company recently received NMPA's approval to initiate a phase II clinical trial for AK112's monotherapy or combo chemotherapy neoadjuvant/adjuvant therapy of resectable NSCLC.

**Expecting commercialisation of AK104.** AK104 is a humanized tetrameric bispecific antibody, which has obtained FDA's fast track and orphan drug, and NMPA breakthrough therapy. In SITC 2021, the company reported the phase II study of AK104 in patients with metastatic nasopharyngeal carcinoma (NPC) who had progressed after two or more lines of chemotherapy. The ORR is 30%, and DCR is 70%. In addition, the median follow-up time was 7.49 months and mPFS was 3.71 months. The ORR of PD-L1 positive and negative patients is 50% and 16.7%, respectively. Meanwhile, the study shows the good safety of AK112 and the incidence of grade 3 TRAEs is 21.7%. In September 2021, the NDA of AK104 used for the treatment of 2L/3L cervical cancer, has been accepted by the NMPA with the priority review designation. We expect AK104 to obtain NMPA's approval in 2022E. To prepare for the commercialisation of AK104, the company currently has a sales team of over 500 sales people and is expected to have 800-1,000 members when AK104 is launched.

**Maintain BUY.** We maintain our EPS forecasts of -Rmb0.85 in 21E, -Rmb0.77 in 22E and Rmb0.06 in 23E. We raise our target price from HK\$55.0 to HK\$62.0. With 22% upside, we maintain our BUY rating.

**Risks:** R&D failure of key pipeline; commercialisation failure of key products.

### Financial summary and valuation

	2019	2020	2021E	2022E	2023E
Revenue (Rmbm)	71	0	283	1,213	2,615
Growth (YoY %)	2,408.10	0.00	-	328.07	115.59
Net profit (Rmbm)	(335)	(1,177)	(698)	(626)	50
Growth (YoY %)	-	-	-	-	-
EPS (Rmb)	(3.26)	(1.65)	(0.85)	(0.77)	0.06
ROE (%)	(155.48)	(34.11)	(19.79)	(24.39)	1.89
Dividend yield (%)	0.00	0.00	0.00	0.00	0.00
PE (x)	-	-	-	-	752.50
PB (x)	21.85	8.34	10.60	14.58	14.23

Note: EPS is calculated as the net profit attributable to shareholders divided by weighted average number of diluted shares.

**投资要点：**

康方生物近期于第 36 届肿瘤免疫治疗学会年会 ( SITC 2021 ) 上公布了 AK104 ( 凯得宁 · PD-1/CTLA-4 双抗 ) 和 AK112 ( PD-1/VEGF 双抗 ) 三项临床研究结果以及 AK104、AK117 ( CD47 ) 和 AK119 ( CD73 ) 三项机制研究成果。

**AK112 · 核心双抗在研品种。** AK112 是潜在全球首创的 PD-1/VEGF 双特异性抗体。该药目前在中国进行多个 Ib/II 期试验，包括肺癌、妇科肿瘤、肝癌等。公司于 11 月 15 日在 SITC 2021 上公布 AK112 的两项临床结果，包括一项针对铂耐药/难治性上皮性卵巢癌 ( PROC ) 患者的 I 期研究和一项关于 AK112 联合奥拉帕利治疗铂敏感复发性 BRCA 生殖系野生型卵巢癌患者的 Ib / II 期临床研究。AK112 在 PROC 患者的 I 期研究结果显示客观缓解率 ( ORR ) 和疾病控制率 ( DCR ) 分别为 29.4% 和 76.5%。中位随访时间为 4.5 个月，3 级及以上治疗相关不良反应 ( TRAEs ) 发生率为 15.8%，无 4-5 级 TRAEs。此外，AK112 联合奥拉帕利 ( PARP 抑制剂 ) 的 Ib/II 期临床研究将评估 AK112 的三个剂量水平 ( 10mg/kg、20mg/kg 和 30mg/kg Q2W ) 联合固定剂量的奥拉帕利 ( 300mg · BID )，以确定 II 期的推荐剂量 ( RP2D )。此外，公司近期获得 NMPA 的批准开展 AK112 关于可切除非小细胞肺癌的单药或联合化疗新辅助/辅助治疗的 II 期临床试验。

**AK104 有望开启商业化。** AK104 是一种人源化四聚体双特异性抗体，已获 FDA 快速通道和孤儿药资格认定，以及 NMPA 突破性疗法认定。公司在 SITC 2021 上发布了 AK104 治疗经二线及以上化疗后进展的转移性鼻咽癌 ( NPC ) 的 II 期临床研究，客观缓解率为 30%，疾病控制率为 70%。此外，中位随访时间为 7.49 个月，中位无进展生存期为 3.71 个月。AK104 治疗 PD-L1 阳性和阴性肿瘤患者的 ORR 分别为 50% 和 16.7%。该研究表明 AK112 具有良好的安全性，3 级 TRAEs 的发生率为 21.7%。今年 9 月，AK104 治疗二三线宫颈癌的上市申请已被 NMPA 受理，并获得优先审评资格。我们预计 AK104 有望于 2022 年获得 NMPA 批准。公司目前拥有超过 500 人的销售团队为 AK104 的商业化做准备，预计在该产品上市时销售团队有望达到 800-1000 人。

**维持买入评级。** 我们维持 2021、2022 和 2023 年的 EPS 预测，分别为 -0.85 元、-0.77 元和 0.06 元。将目标价从 55 港币上调至 62 港币。目标价对应 22% 的上升空间，维持买入评级。

**风险提示：** 关键管线的研发失败；核心产品的商业化失败。

## Company Financials

### Consolidated Income Statement

Rmbm	2019	2020	2021E	2022E	2023E
Revenue	71	0	283	1,213	2,615
Cost of Sales	0	0	(46)	(291)	(523)
Gross Profit	71	0	237	922	2,092
Other Income	50	124	130	80	60
Selling/General/Admi. Expenses	(55)	(253)	(225)	(752)	(1,072)
Ebitda	(232)	(920)	(904)	(856)	201
Ebit	(249)	(942)	(1,004)	(976)	61
Finance Costs	(6)	(8)	(7)	(6)	(8)
<b>Profit before tax</b>	<b>(346)</b>	<b>(1,321)</b>	<b>(993)</b>	<b>(962)</b>	<b>73</b>
Income tax expense	0	0	0	0	(11)
Minority interests	11	144	294	337	(12)
<b>Profit for the year</b>	<b>(335)</b>	<b>(1,177)</b>	<b>(698)</b>	<b>(626)</b>	<b>50</b>

Source: SWS Research

### Consolidated Cash Flow Statement

Rmbm	2019	2020	2021E	2022E	2023E
<b>Profit before taxation</b>	<b>(346)</b>	<b>(1,321)</b>	<b>(993)</b>	<b>(962)</b>	<b>73</b>
Plus: Depr. and amortisation	16	22	100	120	140
Finance cost	6	8	7	6	8
Losses from investments	0	0	0	0	0
Change in working capital	47	(1)	(214)	(292)	(595)
Others	57	674	(86)	(60)	(51)
<b>CF from operating activities</b>	<b>(220)</b>	<b>(618)</b>	<b>(1,186)</b>	<b>(1,188)</b>	<b>(425)</b>
Capex	(236)	(448)	(300)	(200)	(100)
Other CF from investing activities	108	(107)	0	0	0
<b>CF from investing activities</b>	<b>(128)</b>	<b>(556)</b>	<b>(300)</b>	<b>(200)</b>	<b>(100)</b>
Equity financing	319	2,715	1,069	0	0
Net change in liabilities	86	37	0	500	500
Dividend and interest paid	(4)	(3)	(7)	(6)	(8)
Other CF from financing activities	830	130	0	0	0
<b>CF from financing activities</b>	<b>1,230</b>	<b>2,878</b>	<b>1,062</b>	<b>494</b>	<b>492</b>
<b>Net cash flow</b>	<b>883</b>	<b>1,705</b>	<b>(424)</b>	<b>(894)</b>	<b>(33)</b>
FCFF	(421)	(1,369)	(1,418)	(1,348)	(505)
FCFE	(341)	(1,341)	(1,425)	(854)	(13)

Source: SWS Research

**Consolidated Balance Sheet**

Rmbm	2019	2020	2021E	2022E	2023E
<b>Current Assets</b>	1,256	3,001	2,670	2,173	2,836
Bank balances and cash	1,186	2,684	2,261	1,367	1,334
Trade and other receivables	51	144	272	598	1,218
Inventories	16	61	25	96	172
Other current assets	3	112	112	112	112
Long-term investment	3	6	9	12	15
PP&E	214	608	808	888	848
Intangible and other assets	200	241	238	235	232
<b>Total Assets</b>	<b>1,673</b>	<b>3,856</b>	<b>3,725</b>	<b>3,308</b>	<b>3,931</b>
<b>Current Liabilities</b>	120	170	48	653	1,254
Borrowings	38	14	14	514	1,014
Trade and other payables	77	152	31	136	236
Other current liabilities	4	4	4	4	4
Long-term liabilities	1,337	236	149	89	49
<b>Total Liabilities</b>	<b>1,457</b>	<b>406</b>	<b>198</b>	<b>743</b>	<b>1,304</b>
Minority Interests	222	265	(30)	(366)	(354)
Shareholder Equity	(6)	3,186	3,557	2,931	2,981
Share Capital	0	0	0	0	0
Reserves	(6)	3,185	3,557	2,931	2,981
Total Equity	216	3,450	3,527	2,565	2,627
<b>Total Liabilities and equity</b>	<b>1,673</b>	<b>3,856</b>	<b>3,725</b>	<b>3,308</b>	<b>3,931</b>

Source: SWS Research

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Outperform: Share price performance is expected to generate between 10-20% upside.

Hold: Share price performance is expected to generate between 10% downside to 10% upside.

Underperform: Share price performance is expected to generate between 10-20% downside.

SELL: Share price performance is expected to generate more than 20% downside.

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