

科伦博泰生物-B Sichuan Kelun-Biotech Biopharmaceutical

Sac-TMT 在中国递交肺癌 NDA，与默沙东合作优化调整

NDA Submission of Sac-TMT Lung Cancer in China, Optimizing Pipeline Collaboration with Merck

观点聚焦 Investment Focus

维持优于大市 Maintain OUTPERFORM

评级	优于大市 OUTPERFORM
现价	HK\$169.90
目标价	HK\$200.10
HTI ESG	3.0-3.0-3.0
E-S-G: 0-5, (Please refer to the Appendix for ESG comments)	

市值	HK\$22.13bn / US\$2.84bn
日交易额 (3 个月均值)	US\$8.34mn
发行股票数目	130.27mn
自由流通股 (%)	22%
1 年股价最高最低值	HK\$189.30-HK\$72.05
注: 现价 HK\$168.30 为 2024 年 08 月 20 日收盘价	



资料来源: Factset

	1mth	3mth	12mth
绝对值	13.2%	-1.4%	104.0%
绝对值 (美元)	13.4%	-1.3%	105.0%
相对 MSCI China	11.8%	9.3%	105.9%

Rmb mn	Dec-23A	Dec-24E	Dec-25E	Dec-26E
Revenue	1,540	1,755	1,528	2,355
Revenue (+/-)	92%	14%	-13%	54%
Net profit	-574	-230	-1,013	-782
Net profit (+/-)	n.m.	n.m.	n.m.	n.m.
Diluted EPS (Rmb)	-2.84	-1.04	-4.60	-3.55
GPM	65.6%	70.0%	79.6%	80.0%
ROE	-24.6%	-10.9%	-92.9%	-253.9%
P/E	n.m.	n.m.	n.m.	n.m.

资料来源: 公司信息, HTI

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(Please see APPENDIX 1 for English summary)

事件

科伦博泰发布 2024H1 业绩: 收入 13.8 亿元 (+32.2%), 毛利 10.8 亿元 (+59.4%), 研发开支 6.5 亿元 (+33.0%), 期内利润 3.1 亿元 (去年同期为-3113 万元)。截至 2024 年 6 月 30 日, 在手现金及现金等价物 28.9 亿元。

点评

核心产品 sac-TMT 全球多项适应症进入注册性临床, 2 项适应症在中国递交上市申请。 sac-TMT (TROP2 ADC) 的海外合作伙伴默沙东已开展 10 项海外权益, 适应症覆盖乳腺癌、非小细胞肺癌、子宫内膜癌、宫颈癌、胃食管腺癌, 体现 4 种开发策略: 1) 子宫内膜癌、胃食管腺癌等适应症有望推动药物快速上市, 2) EGFR 突变型非小细胞肺癌利用生物标志物富集优势患者, 3) 早期非小细胞肺癌、三阴性乳腺癌、一线非小细胞肺癌的维持治疗尝试升级现有 K 药疗法, 4) 在 1L TPS \geq 50% 非小细胞肺癌、HR+HER2-后线乳腺癌探索 K 药的联用机会。公司在大中华区共有 7 项适应症进入注册性临床, 适应症围绕乳腺癌、非小细胞肺癌。其中 1) 3L+三阴性乳腺癌、3L EGFR 突变非小细胞肺癌适应症分别于 2023 年 12 月、2024 年 8 月递交 NDA, (拟) 纳入优先审评审批程序; 2) 在 PD-L1 阴性三阴性乳腺癌、PD-L1 阳性非小细胞肺癌、PD-L1 阴性非鳞状非小细胞肺癌启动 1L 疗法的 III 期临床。我们预计 sac-TMT 在中国有望在 2024H2-25H1 获批上市。

乳腺癌、肺癌中国数据进一步读出, 显示临床生存获益潜力。

2024 年 ASCO 会议读出 sac-TMT 的两项重要数据: 1) 后线三阴性乳腺癌的 III 期临床数据显示, 与化疗相比, sac-TMT 的 PFS (6.7 月 vs 2.5 月) 和 OS ($p=0.0005$) 均具有统计学意义和临床意义的改善; 2) 1L 野生型非小细胞肺癌的 II 期临床数据显示, 联合 PD-L1 的 Q2W 给药方案下, ORR 77.6%, DCR 100%, 截止时 mPFS 未达到; 在 Q3W 给药方案下, mPFS 15.4 月。我们认为两项临床数据均显示 sac-TMT 有潜力为患者带来临床生存获益。

合作管线优化，默沙东对 SKB571 行使选择权。公司与默沙东就早期管线的合作范围动态调整优化，一方面通过不同靶点的 ADC 管线覆盖更广泛的肿瘤适应症，另一方面应用差异化的分子设计实现疗效、安全性的差异化。近日，默沙东对 SKB571（一款双抗 ADC）行使选择权，并将支付 3750 万美元；未来公司亦可获得开发、销售里程碑付款，及按净销售额计算的分级特许权使用费；公司保留中国内地、香港、澳门地区的权益。同时，默沙东退回 SKB315（CLDN18.2 ADC）的全球权益，公司无需退回已收取的首付款及里程碑付款。据公司公告披露，公司将继续在中国开发 SKB315，并采取合适的方式拓展海外市场。我们认为，考虑 CLDN18.2 ADC 的全球竞争格局、以及 SKB315 当前的开发进度，此次管线退回对当前 SKB315 开发的影响有限。

管线即将迎来兑现期，4 款产品处于 NDA 阶段。公司现有 4 款产品处于 NDA 阶段，并预期在 2024H2-25H1 获批上市，包括核心产品 sac-TMT、A166（HER2 ADC），以及主要产品 A167（PD-L1）、A140（西妥昔单抗生物类似药）。目前，公司已经建立部门架构并组织成熟的商业化团队，专注于三级医院和主流医生；团队当前规模 110+，随具有肿瘤医学背景人才的积极招募，公司预计团队规模将进一步有序、逐步扩张，至 2024 年底扩张至约 400 人。依托于控股股东科伦药业在中国广泛的商业化网络及经验，在公司成熟商业化团队保障下，我们期待公司 4 款产品在商业化阶段的销售表现。

盈利预测及估值

根据公司研发合作进展，我们调整 2024-26 年收入预测 17.6/15.3/23.6 亿元（24-25 前值：13.1/17.1 亿元），同比+14%/-13%/+54%；调整 2024-26 年归母净利润预测-2.3/-10.1/-7.8 亿元（24-25 前值：-5.4/-5.3 亿元）。我们使用 DCF 模型及 2025-2032 财年的现金流预测对公司进行估值，给予加权平均资本成本 9.4%、永续增长率 3.0%，基于 RMB:HDK=1.10 的汇率假设，计算得到目标价为 200.10 港元/股（前值：108.61 港元/股，上调 84%），给予“优于大市”评级。

风险

新药研发风险；新药审评审批风险；新药商业化不及预期风险；合作伙伴相关风险；技术迭代风险。

Table 1 DCF 估值

RMB mn	FY23A	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E
	2023/12/31	2024/12/31	2025/12/31	2026/12/31	2027/12/31	2028/12/31	2029/12/31	2030/12/31	2031/12/31	2032/12/31
Forecast Year			1	2	3	4	5	6	7	8
Time Factor (fraction of year to next FY end)			1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0
Sales	1,540.5	1,754.7	1,528.4	2,355.3	3,625.2	4,594.6	5,690.9	6,941.3	7,769.1	8,738.4
... <i>Growth</i>	91.6%	13.9%	-12.9%	54.1%	53.9%	26.7%	23.9%	22.0%	11.9%	12.5%
Gross Profit	759.2	1,448.6	1,146.3	1,837.1	2,936.4	3,813.5	4,837.3	6,038.9	6,836.8	7,777.2
... <i>GP Margin</i>	49.3%	82.6%	75.0%	78.0%	81.0%	83.0%	85.0%	87.0%	88.0%	89.0%
SG&A	201.4	297.0	535.7	748.6	992.2	1,205.8	1,441.5	1,746.4	1,965.1	2,137.4
... <i>SG&A Margin</i>	13.1%	16.9%	35.1%	31.8%	27.4%	26.2%	25.3%	25.2%	25.3%	24.5%
Depreciation & Amortisation	111.3	119.4	114.1	111.8	118.6	134.1	155.8	183.9	216.5	251.4
EBIT	-383.4	-125.6	-1008.2	-777.2	-110.8	407.0	1083.7	1863.4	2319.9	2959.1
Add: Amortisation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITA	-383.4	-125.6	-1008.2	-777.2	-110.8	407.0	1083.7	1863.4	2319.9	2959.1
... <i>Margin</i>	-24.9%	-7.2%	-66.0%	-33.0%	-3.1%	8.9%	19.0%	26.8%	29.9%	33.9%
... <i>Growth</i>										
Add: Depreciation	111.3	119.4	114.1	111.8	118.6	134.1	155.8	183.9	216.5	251.4
EBITDA	-272.1	-6.2	-894.1	-665.4	7.9	541.0	1,239.4	2,047.3	2,536.4	3,210.5
... <i>Margin</i>	-17.7%	-0.4%	-58.5%	-28.3%	0.2%	11.8%	21.8%	29.5%	32.6%	36.7%
Less: Tax	-106.4	-99.0	0.0	0.0	17.4	-60.3	-161.8	-278.8	-347.2	-443.1
Less: Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Less: Increase of Working Capital	-5,532.5	283.7	979.5	794.2	794.2	794.2	794.2	794.2	794.2	794.2
Less: Capex	-81.0	-92.2	-80.3	-123.8	-190.6	-241.5	-299.2	-364.9	-408.4	-459.4
... <i>Capex:Depreciation</i>	0.7x	0.8x	0.7x	1.1x	1.6x	1.8x	1.9x	2.0x	1.9x	1.8x
Less: Acquisitions	-1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Free Cash Flow	-5,993.3	86.3	5.0	5.0	628.9	1,033.4	1,572.7	2,197.9	2,575.0	3,102.2
... <i>FCF Growth</i>	1165.9%	-101.4%	-94.2%	0.0%	12442.6%	64.3%	52.2%	39.8%	17.2%	20.5%
PV of FCF	-5,993.3	86.3	4.6	4.2	480.5	721.9	1,004.3	1,283.1	1,374.3	1,513.6
WACC										
Risk Free Rate	2.5%									
Market Risk Premium	9.0%									
Equity Beta	1.05									
Cost of Equity	12.0%									
Cost of Debt (Pre-tax)	4.0%									
Cost of Debt (After tax)	3.4%									
Target Debt weight	30.0%									
Target Equity weight	70.0%									
Tax Rate	15.0%									
DCF Valuation										
Sum of PV of FCF										6,386.4
PV of Terminal Value										24417
Enterprise Value										30,803.2
Add: Net Cash 24H1										2,528.3
Equity Value (RMB)										33,331.6
No. of Ord shares (m), fully diluted										184
Value per Share, Rmb										181.52
FX: Rmb/HKD										1.10
WACC	9.4%		Terminal Growth		3.0%	Value per Share, HKD				\$200.10

资料来源: HTI

Table 2 财务报表

Key ratios	2023A	2024E	2025E	2026E
EPS(RMB)	-2.84	-1.04	-4.60	-3.5
BVPS(RMB)	12.69	9.56	4.95	1.4
Operating cash flow per share	0.32	0.82	0.39	0.5
DPS(RMB)	0.00	0.00	0.00	0.0
P/E	-53.80	-146.67	-33.24	-43.0
P/B	12.06	16.01	30.89	109.2
P/S	22.13	19.43	22.31	14.4
EV/EBITDA	-125.30	-5530.77	-38.13	-51.2
Dividend yield	0.00%	0.00%	0.00%	0.00%
Gross margin	49.28%	82.56%	75.00%	78.00%
Net margin	-37.27%	-13.08%	-66.29%	-33.21%
ROE	-24.65%	-10.91%	-92.93%	-253.85%
ROA	-16.36%	-9.43%	-68.75%	-99.94%
ROIC	-11.54%	-4.82%	-26.64%	-25.12%
Revenue growth	91.62%	13.90%	-12.89%	54.09%
EBIT growth	-8.40%	-67.25%	702.98%	-22.91%
Net profit growth	-22.52%	-97.73%	14403.62%	-25.58%
Asset/liability ratio	153.25%	409.67%	211.60%	89.06%
Liquidity ratio	252.93%	639.22%	238.70%	10.96%
Quick ratio	247.25%	629.80%	228.85%	0.62%
Cash ratio	137.73%	912.65%	764.66%	592.60%
AR days	50.88	50.88	50.88	50.8
Inventory days	29.45	29.45	29.45	29.4
Total asset turnover	0.44	0.72	1.04	3.0
Fixed asset turnover	21.93	24.98	21.76	33.5
Cash flow (RMB mn)	2023A	2024E	2025E	2026E
Net profit	-574.13	-229.60	-1013.22	-782.20
Minority interests	0.00	0.00	0.00	0.00
Non-cash expenses	111.27	119.39	114.11	111.80
Non operating income	106.32	97.61	-1.42	-1.42
Change in working capital	5532.53	-283.75	-979.46	-794.22
Operating cash flow	59.56	179.97	86.78	130.24
Assets	-80.98	-92.24	-80.35	-123.81
Investment	-1.27	0.00	0.00	0.00
Others	-2060.00	0.00	0.00	0.00
Investment cash flow	-1025.42	1074.90	-80.35	-123.81
Increase in debts	-394.04	0.00	0.00	0.00
Proceeds from issue of shares	2853.10	492.85	0.00	0.00
Others	-76.77	-5.01	-5.01	-5.01
Financing cash flow	2382.28	487.83	-5.01	-5.01
Net cash inflow	1416.42	1742.71	1.42	1.42

IS (RMB mn)	2023A	2024E	2025E	2026E
Revenue	1540.49	1754.69	1528.45	2355.2
COGS	781.31	306.10	382.11	518.1
GPM (%)	49.28%	82.56%	75.00%	78.00%
Business tax and surcharges	106.44	99.03	0.00	0.0
Tax rate (%)	23%	0%	0%	0%
Operating expense	1232.38	1668.54	2181.60	2641.3
Operating expense ratio (%)	80.00%	95.09%	142.73%	112.15%
EBIT	-383.38	-125.56	-1008.20	-777.1
Financing expense	84.31	5.01	5.01	5.0
Investment profit	0.00	0.00	0.00	0.0
Operating profit	-473.19	-219.95	-1035.26	-804.2
Exceptional income-net	89.81	94.40	27.06	27.0
Pre-tax profit	-467.69	-130.57	-1013.22	-782.2
EBITDA	-272.12	-6.16	-894.09	-665.3
Taxation	106.44	99.03	0.00	0.0
Tax rate (%)	23%	0%	0%	0%
Minority interests	0.00	0.00	0.00	0.0
Net income to ord equity	-574.13	-229.60	-1013.22	-782.2
Financial statement (RMB mn)	2023A	2024E	2025E	2026E
Cash	1568.77	2432.79	2434.21	2435.6
Account receivable	214.76	244.62	213.08	328.3
Inventory	63.03	24.69	30.83	41.8
Other current assets	960.93	-1026.19	-1930.73	-2761.4
Total current assets	2807.49	1675.92	747.39	44.3
Long-term equity investment				
Tangible assets	692.73	750.53	716.77	728.7
Intangible assets	1.34	1.34	1.34	1.3
Total non-current assets	702.27	760.07	726.31	738.3
Total assets	3509.76	2435.98	1473.69	782.6
Short-term debts	510.69	2.69	2.69	2.6
Account payable	523.48	205.09	256.02	347.1
Other current liabilities	75.84	54.41	54.41	54.4
Total current liabilities	1110.00	262.18	313.11	404.2
Long-term debts	64.74	64.74	64.74	64.7
Other long-term liabilities	5.51	5.51	5.51	5.5
Total non-current liabilities	70.25	70.25	70.25	70.2
Total liabilities	1180.26	332.43	383.36	474.5
Common stocks	219.20	222.85	222.85	222.8
Retain earnings reserves	2110.30	1880.70	867.49	85.2
Minority interests	0.00	0.00	0.00	0.0
Total liabilities and equities	3509.76	2435.98	1473.69	782.6

资料来源: wind (20240820close), HTI

APPENDIX 1

Summary

Event. Kelun-Biotech released 2024H1 results: revenue of 1.38 billion yuan (+32.2%), gross profit of 1.08 billion yuan (+59.4%), R&D expenditure of 650 million yuan (+33.0%), and profit for the period of 310 million yuan (-31.13 million yuan in the same period last year). As of June 30, 2024, cash and cash equivalents amounted to 2.89 billion yuan.

Comment.

The core product sac-TMT has initiated 10 global registrational trials, and 2 indications have submitted NDA in China. Merck, the overseas partner of sac-TMT (TROP2 ADC), has initiated 10 global registrational trials covering breast cancer, non-small cell lung cancer, endometrial cancer, cervical cancer, and gastroesophageal adenocarcinoma, reflecting 4 development strategies: 1) first to market opportunities in endometrial cancer, gastroesophageal adenocarcinoma, 2) biomarker enriching strategy in EGFR mutant non-small cell lung cancer, 3) novel treatment approach for Keytruda established SOC in early non-small cell lung cancer, triple negative breast cancer, maintenance treatment of first-line non-small cell lung cancer, and 4) Keytruda combination opportunities in 1L TPS \geq 50% non-small cell lung cancer and HR+HER2- posterior breast cancer. The company has a total of 7 registrational trials in Greater China, including breast cancer and non-small cell lung cancer. Among them, 1) the indications of 3L+ triple-negative breast cancer and 3L EGFR mutant non-small cell lung cancer has submitted NDA in December 2023 and August 2024, respectively, and (proposed to be) included in the priority review; 2) Phase III clinical trial of initiation of 1L therapy in PD-L1-negative triple-negative breast cancer, PD-L1-positive non-small cell lung cancer, and PD-L1-negative non-squamous non-small cell lung cancer. We expect sac-TMT to be approved in China in 2024H2-25H1.

Further data on breast cancer and lung cancer in China showed the potential for clinical survival benefit. Two important data were read out at the 2024 ASCO meeting: 1) phase III clinical data in relapsed triple-negative breast cancer showed statistically significant and clinically meaningful improvements in PFS (6.7 months vs 2.5 months) and OS ($p=0.0005$) with sac-TMT compared with chemotherapy; 2) Phase II clinical data of 1L wild-type non-small cell lung cancer showed that the ORR was 77.6% and the DCR was 100% under the Q2W dosing regimen combined with PD-L1, and the mPFS was not reached at the cut-off; Under the Q3W dosing regimen, mPFS was 15.4 months. We believe that both clinical data show that sac-TMT has the potential to provide clinical survival benefits to patients.

Collaboration pipeline optimization, Merck exercised the option of SKB571. The company and Merck have dynamically adjusted and optimized the scope of the early-stage pipeline, covering a wide range of oncology indications through ADC pipelines with different targets, and differentiating molecular designs to achieve differentiated efficacy and safety. Recently, Merck exercised its option to SKB571, a bispecific antibody ADC, and will pay 37.5 million USD; the company can also receive development and sales milestone payments if event reached, as well as tiered royalties based on net sales; The company reserves the rights in Greater China. At the same time, Merck has returned the global right to SKB315 (CLDN18.2 ADC) without the need to refund the down payment and milestone payments received. According to the company's announcement, the company will continue to develop SKB315 in China and take appropriate ways to expand overseas markets. We believe that this pipeline rollback will have a limited impact on the current SKB315 development, given the global competitive landscape of the CLDN18.2 ADC and the current development schedule of the SKB315.

The pipeline near commercial launch with 4 products in NDA. The company currently has 4 products in the NDA stage and is expected to be approved in 2024H2-25H1, including the core products sac-TMT and A166 (HER2 ADC), and the main products A167 (PD-L1) and A140 (cetuximab biosimilars). At present, the company has established a departmental structure and organized a mature commercialization team, focusing on tertiary hospitals and KOLs. The current team size is 110+, and with the active recruitment of talents with oncology background, the company expects the team size to further expand in an orderly and gradual manner, expanding to about 400 people by the end of 2024. Relying on the extensive commercialization network and experience of the controlling shareholder, Kelun Pharmaceutical, and with the execution of the company's mature commercialization team, we look forward to the sales performance of the company's four products in the commercialization stage.

Earnings Forecast and Valuation. According to progress in Merck collaboration, we adjust our 2024-26 revenue forecast to 1.76/1.53/2.36 billion yuan (24-25 prior: 1.31/1.71 billion yuan), +14%/-13%/+54% YoY. We adjust 2024-26 net profit attributable to the parent company to -230/-1013/-782 million yuan (prior: -540/530 million yuan). We value the company using the DCF model and cash flow projections for fiscal year 2025-2032, giving a WACC of 9.4% and a terminal growth rate of 3.0%, and based on exchange rate assumptions of RMB:HKD=1.10:1, target price to be 200.10 HKD/share (prior: 108.61HKD/share, up 84%) and an "outperform" rating.

Risks. Risks in innovative drug R&D, risks in new drug approval, risks in new drug commercialization, risks in product iteration, risks related with partnership, risks in continuous loss and short-term cash dividend.

APPENDIX 2

ESG Comments

Environmental:

dedication on environment improvement

Social:

providing products with clinical benefit

Governance:

clear information disclosure

附录 APPENDIX

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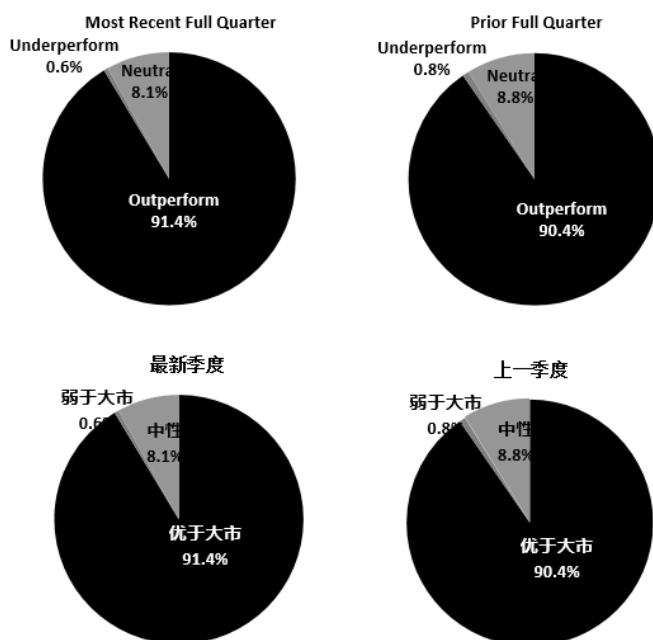
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