

康哲药业 China Medical System Holdings (867 HK)

集采下业绩承压，创新管线陆续迎来转化

Earnings Under Pressure Due to VBP, Expecting Transformation of Innovative Pipeline

观点聚焦 Investment Focus

维持优于大市 Maintain OUTPERFORM

评级	优于大市 OUTPERFORM
现价	HK\$7.10
目标价	HK\$9.90
HTI ESG	2.0-2.5-4.0
E-S-G: 0-5, (Please refer to the Appendix for ESG comments)	
市值	HK\$17.41bn / US\$2.22bn
日交易额 (3 个月均值)	US\$8.61mn
发行股票数目	2,452mn
自由流通股 (%)	50%
1 年股价最高最低值	HK\$15.70-HK\$7.00

注：现价 HK\$7.10 为 2024 年 4 月 23 日收盘价



资料来源: Factset

	1mth	3mth	12mth
绝对值	-42.6%	-37.4%	-44.6%
绝对值 (美元)	-42.7%	-37.5%	-44.5%
相对 MSCI China	-5.5%	1.0%	1.6%

(Rmb mn)	Dec-21A	Dec-22A	Dec-23E	Dec-24E
营业收入	8,337	9,150	9,410	10,129
(+/-)	20%	10%	3%	8%
净利润	3,025	3,276	3,355	3,585
(+/-)	16%	8%	2%	7%
全面摊薄 EPS (Rmb)	1.22	1.33	1.36	1.46
毛利率	74.9%	76.9%	74.3%	75.8%
净资产收益率	23.7%	22.3%	20.2%	19.1%
市盈率	6	5	5	5

资料来源: 公司信息, HTI

(Please see APPENDIX 1 for English summary)

事件

康哲药业公布 2023 年业绩：营业额 80.1 亿元 (-12.4%)；若全按药品销售收入计算，营业额 94.7 亿元 (-9.8%)。毛利率 76.2% (-0.7pct)；销售费用 25.1 亿元 (-7.7%)，销售费用率 31.3% (+1.4pct)；管理费用 6.6 亿 (+3.1%)，管理费用率 8.2% (+1.2pct)；研发开支 8.2 亿元，其中费用化研发支出 2.0 亿元 (+55.8%)，研发费用率 2.4% (+1.0pct)。年度溢利 23.8 亿元 (-27.2%)，净利润率 29.8% (-6.0pct)；剔除相关资产减值损失计提后，正常化年度溢利为 27.1 亿元 (-18.8%)。整体低于预期。

点评

3 款产品均已执行集采，收入端的负面影响有望在 2024 年内充分消化。 2022-2023 年执行的第七批和第八批集采分别涉及黛力新、波依定及优思弗。根据公司业绩会披露，3 款产品在集采前（全按药品销售收入计算）合计约 50 亿；2023 年在集采影响下三款产品销售额下降约 17 亿元。参考黛力新集采执行一年余销售表现，我们预计：1) 3 款产品收入受到集采的负面影响有望在 2024H1 消化充分；2) 假设价格稳定，3 款产品销售额合计的保留率约为 50%。

4 款创新药纳入医保，预期将依托开放式商业化平台实现放量。 2023 年至今，公司在心脑血管线新增商业化品种地西洋鼻喷雾和蔗糖羟基氧化铁咀嚼片，在消化/自免线新增商业化品质甲氨蝶呤注射液及替瑞奇珠单抗，并均已纳入医保。根据股权激励目标，地西洋鼻喷雾、蔗糖羟基氧化铁咀嚼片、甲氨蝶呤注射液在 2024-26 年累计销售收入 25 亿元；替瑞奇珠单抗将纳入康哲美丽拟成立的激励计划。我们认为，在纳入医保目录及心脑血管、消化等专科资源的支持下，4 款创新产品有望实现良好放量并达成股权激励目标。

预计 2024-26 年 3 款创新产品上市，芦可替尼乳膏指引 50+亿峰值。 公司在研管线中，亚甲蓝肠溶液、德度司他片的 NDA 已分别于 2023 年 2 月及 2024 年 4 月获得受理，我们预计两款产品分别在 2024、2025 年获批；芦可替尼乳膏已开展真实世界研究并获得 III 期临床试验批件，我们认为该产品有望最早于 2025 年获批上市（白癜风适应症）。芦可替尼是美国 FDA 和欧洲 EMA 批准的首个且唯一局部 JAK 抑制剂白癜风复色产品。在中国，约 1400 万患者患有白癜风，目前缺乏针对复色的有效药物；若顺利获批，芦可替尼有望打开国内白癜风复色治疗的蓝海市场，公司指引峰值 50 亿美元。

孟科含 Kehan Meng
kh.meng@htisec.com

袁艺琳 Yilin Yuan
yl.yuan@htisec.com

盈利预测及估值

考虑集采进程、医疗行业政策变化、新产品医保内放量，我们调整 2024-25E 收入为 79.2/91.3 亿元（2024E 前值：101.3 亿元），同比-1/+15%；考虑公司产品结构带来的毛利率变化、创新转型的研发投入、创新药市场推广的投入，我们调整 2024-25E 归母净利润为 18.2/20.1 亿元（2024E 前值：35.9 亿元），同比-23/+10%。参考可比公司华东医药（17x）、中国生物制药（14x）、石药集团（10x），结合公司有潜在重磅产品芦可替尼已经处于临床开发后期，我们给予公司 12x PE（2024 年），对应股价 9.90 港元/股（前值：17.57 港元/股，下调：-43.6%），维持评级“优于大市”。

风险

新药研发风险，新药审评审批风险，新药商业化风险，医疗反腐相关政策变化，产品集采风险。

Table 1 可比公司估值

Ticker	Company	Price	EPS				PE			
			2022A	2023A	2024E	2025E	2022A	2023A	2024E	2025E
000963.SZ	华东医药	32.99	1.42	1.62	1.95	2.29	23.23	20.36	16.92	14.41
1093.HK	石药集团	5.49	0.51	0.49	0.56	0.63	10.76	11.20	9.80	8.71
1177.HK	中国生物制药	2.30	0.12	0.13	0.15	0.17	17.41	16.07	13.93	12.29
	Average						17.13	15.88	13.55	11.80

资料来源: wind 一致预期 (20240423close) HTI

Table 2 财务报表

Key ratios	2022A	2023A	2024E	2025E	Financial statement (Rmb mn)	2022A	2023A	2024E	2025E
EPS(Rmb)	1.28	0.98	0.75	0.83	Cash	4376.38	4311.06	4860.24	5007.78
BVPS(Rmb)	5.95	6.33	6.78	7.27	Account receivable	1711.61	1604.53	1638.13	1889.12
Operating cash flow per share(Rmb)	1.45	1.02	0.86	0.76	Inventory	47720.60%	63763.60%	55855.03%	64404.98%
DPS(Rmb)	0.51	0.39	0.30	0.33	Other current assets	2264.18	2241.21	2262.27	2262.27
					Total current assets	8829.38	8794.44	9319.19	9803.22
Gross margin	76.89%	76.24%	75.90%	75.90%	Long-term equity investment				
Net margin	34.34%	29.92%	23.18%	22.18%	Tangible assets	3540.07	3745.67	3725.61	3726.45
ROE	21.54%	15.45%	11.04%	11.36%	Construction in progress				
ROA	17.70%	13.52%	9.68%	10.00%	Intangible assets	2066.42	2216.09	2580.64	2982.88
ROIC	15.46%	11.55%	8.14%	8.45%	Total non-current assets	8924.61	8936.40	9645.43	10450.75
Revenue growth	9.75%	-12.43%	-1.20%	15.32%	Total assets	17753.99	17730.84	18964.62	20253.97
EBIT growth	6.04%	-24.24%	-20.14%	10.16%	Short-term debts	1799.14	1285.07	1285.07	1285.07
Net profit growth	4.44%	-24.63%	-23.46%	10.34%	Account payable	726.97	436.98	583.15	672.42
Asset/liability ratio	588.57%	815.42%	817.23%	840.46%	Prepayments	1.00	1.00	1.00	1.00
Liquidity ratio	306.88%	429.25%	424.57%	429.17%	Other current liabilities	350.00	325.74	325.74	325.74
Quick ratio	290.30%	398.13%	399.13%	400.97%	Total current liabilities	2877.10	2048.79	2194.96	2284.23
Cash ratio	152.11%	210.42%	221.43%	219.23%	Long-term debts				
AR days	71.02	75.52	75.52	75.52	Other long-term liabilities	139.36	125.64	125.64	125.64
Inventory days	81.98	106.85	106.85	106.85	Total non-current liabilities	139.36	125.64	125.64	125.64
Total asset turnover	0.52	0.45	0.42	0.45	Total liabilities	3016.46	2174.43	2320.60	2409.87
Fixed asset turnover	1.03	0.90	0.82	0.87	Common stocks	14589.07	15520.21	16620.45	17834.48
IS (Rmb mn)	2022A	2023A	2024E	2025E	Retain earnings reserves	14505.08	15436.22	16536.46	17750.49
Revenue	9150.35	8013.30	7916.92	9129.93	Minority interests	148.01	36.20	23.56	9.62
COGS	2114.50	1904.12	1907.98	2200.04	Total liabilities and equities	17753.54	17730.84	18964.62	20253.97
GPM (%)	76.89%	76.24%	75.90%	75.90%	Cash flow (Rmb mn)	2022A	2023A	2024E	2025E
Business tax and surcharges	486.66	489.34	374.53	413.27	Net profit	3159.73	2381.44	1822.72	2011.21
Tax rate (%)	13%	17%	17%	17%	Minority interests	17.20	-16.51	-12.64	-13.94
Operating expense	3357.92	3167.97	3541.54	4129.82	Non-cash expenses				
Operating expense ratio (%)	36.70%	39.53%	44.73%	45.23%	Non operating income				#REF!
Administrative expense					Change in working capital	-230.34	343.34	-191.66	247.22
Administrative expense ratio (%)					Operating cash flow	3553.24	2502.85	2116.93	1866.69
EBIT	3695.47	2799.80	2235.80	2463.02	Assets	-18.34	-43.19	-65.00	-65.00
Financing expense	49.09	46.25	38.54	38.54	Investment	-1169.05	-759.64	-729.09	-804.48
Financing expense ratio (%)	0.54%	0.58%	0.49%	0.42%	Others	9.18	360.56	0.00	0.00
Assets impairment loss					Investment cash flow	-1178.20	-442.28	-794.09	-869.48
Investment profit	65.06	395.09	277.87	277.87	Increase in debts	-69.83	-514.08	0.00	0.00
Operating profit	3552.49	2746.08	1957.93	2185.16	Proceeds from issue of shares	-48.38	0.00	0.00	0.00
Exceptional income-net					Others	-1281.70	-1610.95	-773.65	-849.67
Pre-tax profit	3646.39	2870.78	2197.25	2424.48	Financing cash flow	-1399.91	-2125.02	-773.65	-849.67
EBITDA	3922.70	3029.37	2299.80	2527.18	Net cash inflow	975.13	-64.45	549.19	147.53
Taxation	486.66	489.34	374.53	413.27					
Tax rate (%)	13%	17%	17%	17%					
Minority interests	17.20	-16.51	-12.64	-13.94					
Net income to ord equity	3142.53	2397.95	1835.36	2025.16					

资料来源: HTI

APPENDIX 1

Summary

Event.

CMS announced its 2023 results: revenue of RMB8.0 billion (-12.4%) while RMB9.5 billion (-9.8%) based on drug sales revenue. Gross profit margin was 76.2% (-0.7pct), selling expenses were RMB2.5 billion (-7.7%), selling expense ratio was 31.3% (+1.4 pct), administrative expenses were RMB657 million (+3.1%), administrative expense ratio was 8.2% (+1.2 pct), and R&D expenditures were RMB816 million, of which R&D expense was RMB195 million (+55.8%) and R&D expense ratio was 2.4% (+1.0pct). Profit for the year was RMB2.4 billion (-27.2%), net profit margin was 29.8% (-6.0pct) and normalized profit for the year was RMB2.7 billion (-18.8%) excluding the provision for impairment losses on related assets. Overall below expectations.

Comment.

All three products have been affected by VBP, and the negative impact on the revenue is expected to be fully absorbed in 2024. The seventh and eighth batches of VBP implemented in 2022-2023 involve Dailixin, Boyiding and Yousifu. According to the company's earnings call, the total sales of the three products before centralized procurement (calculated based on drug sales revenue) will be about RMB5 billion, and the sales of the three products has decline by about RMB1.7 billion in 2023 under the influence of VBP. Referring to the sales performance of Dailixin during VBP for more than one year, we expect that: 1) the negative impact of the revenue of the three products is expected to be fully absorbed in 2024H1, and 2) the total retention rate of the sales of the three products will be about 50% assuming stable prices.

Four innovative drugs have been included in the NRDL, and we expect a smooth sales ramp-up with CMS's commercialization platform. Since 2023, the company has added commercial varieties diazepam nasal spray and sucrose hydroxyl iron oxide chewable tablets in the cardiovascular and cerebrovascular line, as well as methotrexate injection and tildrakizumab in the digestive/autoimmune line, all of which have been included in the NRDL. According to the equity incentive target, diazepam nasal spray, sucrose hydroxyl iron oxide chewable tablets, and methotrexate injection is expected have a cumulative sales revenue of RMB2.5 billion in 2024-26, and tildrakizumab will be included in the incentive plan to be established by CMS Skinhealth. We believe that with the support of the inclusion of the NRDL and specialist resources within therapeutic areas, the four innovative products are expected to achieve good volume growth and achieve the goal of equity incentives.

We expected additional 3 innovative products to be launched in 2024-26, and guidance for ruxolitinib cream peak sales is RMB5+ billion. Within the company's R&D pipeline, the NDAs of methylene blue intestine solution and desidustat tablets have been accepted in February 2023 and April 2024, respectively, and we expect the two products to be approved in 2024 and 2025, respectively. Ruxolitinib cream is under RWS and has been approved for Phase III clinical trials, and we expect the product to be approved for marketing (vitiligo indication) as early as 2025. Ruxolitinib is the first and only topical JAK inhibitor vitiligo repigmentation product approved by the FDA and the EMA. In China, where about 14 million patients suffer from vitiligo, there is currently a lack of effective drugs for repigmentation, and if approved, ruxolitinib is expected to open up the blue ocean market for vitiligo repigmentation treatment in China, with the company guiding a peak of RMB5+ billion.

Earnings Forecast and Valuation.

Considering the VBP impact, changes in medical industry policies, and the NRDL inclusion of new products, we adjust the 2024-25E revenue to RMB7.9/9.1 billion (2024E previous value: RMB10.1 billion), a year-on-year increase of -1/+15%; Considering the changes in gross profit margin brought about by product mix, R&D investment in innovative pipeline, and investment in innovative drug marketing, we adjust the net profit attributable to the parent company in 2024-25E to RMB1.8/2.0 billion (2024E previous value: RMB3.6 billion), a year-on-year increase of -23/+10%. Referring to comparable companies Huadong Pharmaceutical (17x), Sino Biopharmaceutical (14x), and CSPC Pharmaceutical Group (10x), combined with the company's potential blockbuster product ruxolitinib is already in the late stage of clinical development, we give the company 12x PE (2024), corresponding to a stock price of HK\$9.90/share (previous value: HK\$17.57/share, downgrade: -43.6%), and maintain the rating of "outperform".

Risks.

Risk of VBP of key products. Risk of commercialization fell short. Risks in R&D and registration. Risks of policy related with anti-corruption in healthcare system.

APPENDIX 2

ESG Comments

Environmental:

Environmental friendly manufacturing facilities

Social:

innovative medicine addressing clinical need

Governance:

internal transfer of commercial staff to innovative products to maximize productivity

附录 APPENDIX

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分析师股票评级

优于大市，未来 12-18 个月内预期相对基准指数涨幅在 10%以上，基准定义如下

中性，未来 12-18 个月内预期相对基准指数变化不大，基准定义如下。根据 FINRA/NYSE 的评级分布规则，我们会将中性评级划入持有这一类别。

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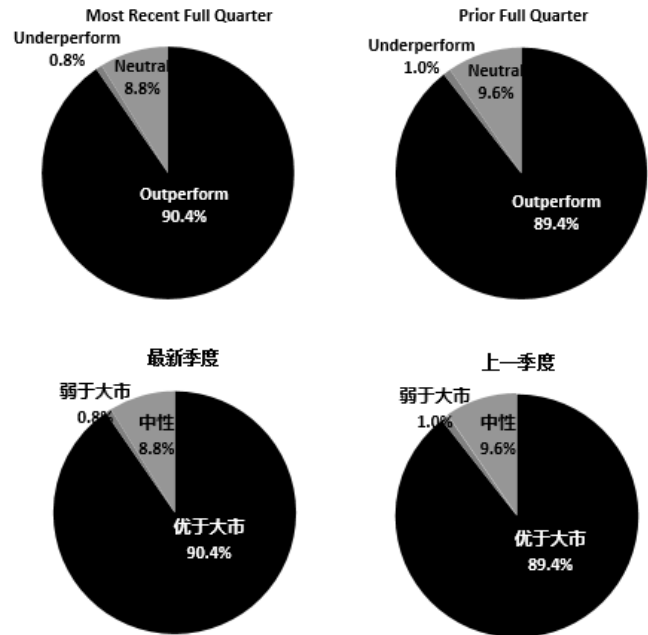
Analyst Stock Ratings

Outperform: The stock's total return over the next 12-18 months is expected to exceed the return of its relevant broad market benchmark, as indicated below.

Neutral: The stock's total return over the next 12-18 months is expected to be in line with the return of its relevant broad market benchmark, as indicated below. For purposes only of FINRA/NYSE ratings distribution rules, our Neutral rating falls into a hold rating category.

Underperform: The stock's total return over the next 12-18 months is expected to be below the return of its relevant broad market benchmark, as indicated below.

Benchmarks for each stock's listed region are as follows: Japan – TOPIX, Korea – KOSPI, Taiwan – TAIEX, India – Nifty100, US – SP500; for all other China-concept stocks – MSCI China.



截至 2024 年 3 月 31 日海通国际股票研究评级分布

	优于大市	中性 (持有)	弱于大市
海通国际股票研究覆盖率	90.4%	8.8%	0.8%
投资银行客户*	3.3%	4.9%	0.0%

*在每个评级类别里投资银行客户所占的百分比。

上述分布中的买入，中性和卖出分别对应我们当前优于大市，中性和落后大市评级。

只有根据 FINRA/NYSE 的评级分布规则，我们才将中性评级划入持有这一类别。请注意在上表中不包含非评级的股票。

此前的评级系统定义（直至 2020 年 6 月 30 日）：

买入，未来 12-18 个月内预期相对基准指数涨幅在 10%以上，基准定义如下

中性，未来 12-18 个月内预期相对基准指数变化不大，基准定义如下。根据 FINRA/NYSE 的评级分布规则，我们会将中性评级划入持有这一类别。

卖出，未来 12-18 个月内预期相对基准指数跌幅在 10%以上，基准定义如下

各地股票基准指数：日本 – TOPIX, 韩国 – KOSPI, 台湾 – TAIEX, 印度 – Nifty100; 其他所有中国概念股 – MSCI China.

Haitong International Equity Research Ratings Distribution, as of March 31, 2024

	Outperform	Neutral (hold)	Underperform
HTI Equity Research Coverage	90.4%	8.8%	0.8%
IB clients*	3.3%	4.9%	0.0%

*Percentage of investment banking clients in each rating category.

BUY, Neutral, and SELL in the above distribution correspond to our current ratings of Outperform, Neutral, and Underperform.

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Previous rating system definitions (until 30 Jun 2020):

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NEUTRAL: The stock's total return over the next 12-18 months is expected to be in line with the return of its relevant broad market benchmark, as indicated below. For purposes only of FINRA/NYSE ratings distribution rules, our Neutral rating falls into a hold rating category.

SELL: The stock's total return over the next 12-18 months is expected to be below the return of its relevant broad market benchmark, as indicated below.

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研究机构名称: Haitong Securities India Private Limited

SEBI 研究分析师注册号: INH000002590

地址: 1203A, Floor 12A, Tower 2A, One World Center

841 Senapati Bapat Marg, Elphinstone Road, Mumbai 400 013, India

CIN U74140MH2011FTC224070

电话: +91 22 43156800 传真: +91 22 24216327

合规和申诉办公室联系人: Prasanna Chandwaskar; 电话: +91 22 43156803; 电子邮箱: prasanna.chandwaskar@htisec.com

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Name of the entity: Haitong Securities India Private Limited

SEBI Research Analyst Registration Number: INH000002590

Address : 1203A, Floor 12A, Tower 2A, One World Center

841 Senapati Bapat Marg, Elphinstone Road, Mumbai 400 013, India

CIN U74140MH2011FTC224070

Ph: +91 22 43156800 Fax:+91 22 24216327

Details of the Compliance Officer and Grievance Officer : Prasanna Chandwaskar : Ph: +91 22 43156803; Email id: prasanna.chandwaskar@htisec.com

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China Medical System Holdings - 867 HK



1. 28 Mar 2022 OUTPERFORM at 12.56 target 17.75.
2. 24 Aug 2022 OUTPERFORM at 11.48 target 17.75.
3. 20 Mar 2023 OUTPERFORM at 12.34 target 17.75.
4. 5 Jun 2023 OUTPERFORM at 12.04 target 17.75.
5. 29 Aug 2023 OUTPERFORM at 11.34 target 17.57.

Source: Company data Bloomberg, HTI estimates