

康诺亚生物 Keymed Biosciences (2162 HK)

CM310 有望 2023 年内申请上市，积极合作加速管线全球开发

CM310 Expected to Submit NDA Within 2023, Worldwide Cooperation Advancing Pipeline Development

观点聚焦 Investment Focus

维持优于大市 Maintain OUTPERFORM

评级	优于大市 OUTPERFORM
现价	HK\$50.00
目标价	HK\$77.52
HTI ESG	2.7-3.0-3.0
E-S-G: 0-5	
义利评级	

市值	HK\$13.99bn / US\$1.78bn
日交易额 (3 个月均值)	US\$8.03mn
发行股票数目	279.74mn
自由流通股 (%)	56%
1 年股价最高最低值	HK\$79.20-HK\$32.35

注：现价 HK\$50.00 为 2023 年 8 月 25 日收盘价



资料来源: Factset

	1mth	3mth	12mth
绝对值	0.1%	-6.4%	54.6%
绝对值 (美元)	-0.3%	-6.5%	54.6%
相对 MSCI China	7.5%	-4.4%	66.5%

(Rmb mn)	Dec-22A	Dec-23E	Dec-24E	Dec-25E
营业收入	100	327	159	656
(+/-)	-9%	227%	-51%	311%
净利润	-308	-238	-527	-533
(+/-)	n.m.	n.m.	n.m.	n.m.
全面摊薄 EPS (Rmb)	-1.15	-0.90	-1.98	-2.01
毛利率	97.4%	90.0%	70.0%	75.0%
净资产收益率	-9.2%	-7.7%	-17.9%	-21.5%
市盈率	n.m.	n.m.	n.m.	n.m.

资料来源: 公司信息, HTI

(Please see APPENDIX 1 for English summary)

事件

康诺亚生物发布 23H1 业绩，收入 3.27 亿元 (+227%)，主要来自授权阿斯利康的合作收入。研发费用 2.50 亿元 (+52%)，管理费用 0.82 亿元 (+61%)。净利润 0.47 亿元。截至 2023 年 6 月 31 日，公司在手现金 29.79 亿元。

点评

中国自免/炎症疾病蓝海市场，公司在国产同类药物中布局领先。我们预计中国自免/炎症生物药市场将以 CAGR 30% 的增长速度在 2030 年达到 878 亿元，主要驱动因素包括：1) 新适应症的支付意愿根强；2) 更早纳入医保加速放量；3) 药厂更重视投入患者教育。种种因素将兑现自免/炎症药物在国内庞大患者池的商业潜力。康诺亚生物拥有 CM310 (IL-4Rα)、CM326 (TSLP)、CM336 (MASP-2) 三款处于临床阶段的自免领域候选药物，覆盖特应性皮炎、慢性鼻窦炎伴鼻息肉、哮喘、慢性阻塞性肺疾病、季节性过敏性鼻炎、IgA 肾病等多种自身免疫性疾病，研发进度均处国产同类药物前三。

核心产品 CM310 有望 2023 年内申报上市，商业化团队有序搭建。CM310 是公司自主研发的 IL-4Rα 单抗，与度普利尤单抗为同靶点药物，目前中重度特应性皮炎、慢性鼻窦炎伴鼻息肉适应症均已完成 III 期入组。其中，中重度特应性皮炎适应症的 III 期已宣布达到主要临床终点，目前处于随访阶段。公司预期将分别在 2023 年内及 2024H1 向 CDE 递交中重度特应性皮炎及慢性鼻窦炎伴鼻息肉的 NDA。随 CM310 临近上市的关键节点，公司于中报业绩会中披露，目前公司商业化团队人员正在陆续到位，为后续运营打下良好基础。

积极合作以加快管线商业化进程，CLDN18.2 ADC 全球授权阿斯利康。在国产同类别药物或同靶点药物中，公司候选药物具有高度生物活性及特异性并且进度领先，均处于中国和/或美国 IND 批准的前 3 位。公司积极通过外部合作加速管线研发及商业化进程，以最大化候选药物的商业化潜力。2023 年初公司就 CMG901 (CLDN18.2 ADC) 达成全球独家授权协议。据公司披露，阿斯利康计划在全球范围内开展多项注册性临床，目前正处于项目交接阶段。此外，公司还与石药集团就 CM310 及 CM326 (TSLP) 呼吸系统疾病相关适应症中国内地权益达成合作，目前 CM310 的中重度哮喘适应症已启动关键 II/III 期临床试验，CM326 已启动中重度哮喘的 II 期临床。此外，肿瘤管线 CM369 (CCR8) 及 CM335 (CD20*CD3) 均与诺诚健华合作进行开发，目前处于临床早期开发阶段。

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估值

考虑公司 CM310、CM326 的管线研发及申报进度调整，以及外部合作收入的确认情况，我们对公司盈利预测及估值进行调整。我们预测 2023-25E 收入分别为 3.27/1.59/6.56 亿元（前值：2023-25E 分别为 2.0/1.2/3.0 亿元）。采用 DCF 估值法，WACC 10.0%，永续增长率 3.0%不变，假设汇率 RMB: HKD=1:1.10，我们调整目标价至 77.52 HKD/股（前值：83.75 HKD/股，-7.4%），维持“优于大市”评级。

风险

慢病渗透速度未如理想的风险，新药研发风险，新药审批风险，新药商业化不及预期风险，技术迭代风险，持续亏损及短期内无法现金分红风险。

Table 1 DCF 估值模型

Rmb mn	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E
	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Forecast Year	1	2	3	4	5	6	7	8	9	10
Time Factor (fraction of year to next FY end)	0.3	1.3	2.3	3.3	4.3	5.3	6.3	7.3	8.3	9.3
Sales	327	159	656	1,473	2,881	3,312	4,127	4,276	4,897	5,760
... Growth	0.0%	0.0%	311.4%	124.7%	95.5%	15.0%	24.6%	3.6%	14.5%	17.6%
Gross Profit	294.4	111.6	491.8	1,149.2	2,304.6	2,715.6	3,466.5	3,634.5	4,162.6	4,896.0
... GP Margin	90.0%	70.0%	75.0%	78.0%	80.0%	82.0%	84.0%	85.0%	85.0%	85.0%
SG&A	134	191	230	295	403	431	454	470	539	634
... SG&A Margin	-40.9%	-120.0%	-35.0%	-20.0%	-14.0%	-13.0%	-11.0%	-11.0%	-11.0%	-11.0%
Depreciation & Amortisation	94	109	105	101	98	96	94	92	90	89
EBIT	-281	-571	-577	-303	409	908	1,516	1,701	2,347	2,943
Add: Amortisation	0	0	0	0	0	0	0	0	0	0
EBITA	-281	-571	-577	-303	409	908	1,516	1,701	2,347	2,943
... Margin	-85.9%	-357.9%	-88.0%	-20.6%	14.2%	27.4%	36.7%	39.8%	47.9%	51.1%
... Growth										
Add: Depreciation	94	109	105	101	98	96	94	92	90	89
EBITDA	-187	-462	-472	-202	507	1,004	1,610	1,793	2,438	3,032
... Margin	-57.2%	-289.8%	-72.0%	-13.7%	17.6%	30.3%	39.0%	41.9%	49.8%	52.6%
Less: Tax	0.0	0.0	0.0	0.0	-67.7	-142.7	-233.8	-261.6	-358.5	-447.9
Less: Minority Interests	0.2	0.5	0.5	0.3	-0.4	-0.8	-1.3	-1.5	-2.0	-2.5
Less: Increase of Working Capital	11.8	23.4	-22.0	-49.9	-106.5	-39.1	-68.7	-18.7	-43.5	-60.4
Less: Capex	-300.0	-80.0	-80.0	-80.0	-80.0	-80.0	-80.0	-80.0	-80.0	-80.0
... Capex:Depreciation	3.2x	0.7x	0.8x	0.8x	0.8x	0.8x	0.9x	0.9x	0.9x	0.9x
Less: Acquisitions	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Free Cash Flow	-475	-518	-574	-331	252	741	1,226	1,431	1,953	2,441
... FCF Growth	-92.4%	9.1%	10.7%	-42.3%	-176.2%	193.8%	65.3%	16.7%	36.5%	25.0%
PV of FCF	-460	-456	-459	-241	167	446	670	711	882	1,002
WACC										
Risk Free Rate	3.0%									
Market Risk Premium	10.0%									
Equity Beta	0.91									
Cost of Equity	12.1%									
Cost of Debt (Pre-tax)	6.0%									
Cost of Debt (After tax)	5.1%									
Target Debt weight	30.0%									
Target Equity weight	70.0%									
Tax Rate	15.0%									
DCF Valuation										
Sum of PV of FCF										2,261.2
PV of Terminal Value										14,741.7
Enterprise Value										17,002.9
Add: Net Cash 23H1										2,711.9
Equity Value										19,714.8
No. of Ord shares (m), fully diluted										279.7
Value per Share, Rmb										70.5
FX: Rmb/HKD										1.10
WACC	10.0%		Terminal Growth		3.0%		Value per Share, HKD			\$77.52

资料来源: HTI

Table 2 核心产品估值法 (PS 法)

SOTP估值法			
自行商业化管线: 使用PS估值法			
产品	风险调整后销售峰值 (RMB mn)	PS (x)	估值 (RMB mn)
CM310 (特应性皮炎)	3,932	2.5	9,830
CM310 (CRSwNP)	729	2.5	1,823
CM310 (过敏性鼻炎)	278	2.5	696
CM326 (特应性皮炎)	168	2.5	419
特许权利使用费: 使用PE估值法			
产品	风险调整后分成峰值 (RMB mn)	P/E (x)	估值 (RMB mn)
CM310 (哮喘)	217	5	1,084
CM310 (COPD)	164	5	820
CM326 (哮喘)	249	5	1,246
CMG901 (2/3L 胃癌)	5	5	25
CMG901 (1L 胃癌)	8	5	39
管线估值 (RMB mn)	15,919		
现金价值 (RMB mn)	3,065		
公司估值 (RMB mn)	18,983		
汇率 (HKD:RMB)	1.10		
公司估值 (HKD mn)	20,881		

资料来源: HTI

Table 3 财务报表

主要财务指标	2022A	2023E	2024E	2025E	利润表 (百万元)	2022A	2023E	2024E	2025E
每股指标 (元)					营业总收入	100	327	159	656
每股收益	-1.15	-0.90	-1.98	-2.01	营业成本	3	33	48	164
每股净资产	12.49	11.87	11.25	9.48	毛利率%	97%	90%	70%	75%
每股经营现金流	-1.50	-0.96	-2.06	-1.92	管理费用	134	134	191	230
每股股利	0.00	0.00	0.00	0.00	管理费用率%	134%	41%	120%	35%
盈利能力指标 (%)					EBIT	-348	-281	-571	-577
毛利率	97%	90%	70%	75%	财务费用	8	9	9	9
净利润率	-255%	-73%	-331%	-81%	财务费用率%	8.39%	2.85%	5.86%	1.42%
净资产收益率	-9%	-8%	-18%	-22%	资产减值损失	36	94	109	105
资产回报率	-8%	-7%	-19%	-24%	投资收益	0	0	0	0
投资回报率	-5%	-4%	-11%	-14%	营业利润	-544	-306	-518	-525
盈利增长 (%)					营业外收支	52	52	52	52
营业收入增长率	-9%	227%	-51%	311%	利润总额	-304	-238	-528	-534
EBIT增长率	-91%	-19%	103%	1%	EBITDA	-311	-187	-462	-472
净利润增长率	-14%	-7%	122%	1%	所得税	0	0	0	0
偿债能力指标					有效所得税率%	15%	15%	15%	15%
资产负债率	15%	20%	7%	4%	少数股东损益	4.52	-0.24	-0.53	-0.53
流动比率	872%	2392%	3901%	1594%	归属母公司所有者净利润	-308	-238	-527	-534
速动比率	836%	2392%	3901%	1594%	资产负债表 (百万元)	2022A	2023E	2024E	2025E
现金比率	775%	2153%	3422%	1274%	货币资金	2943	2390	1770	1185
经营效率指标					应收账款及应收票据	0	33	16	66
应收账款周转天数	0.0	36.5	36.5	36.5	存货	44	0	0	0
存货周转天数	347.9	347.9	347.9	347.9	其它流动资产	0	0	0	0
总资产周转率	3%	9%	6%	29%	流动资产合计	3310	2655	2018	1483
固定资产周转率	18%	43%	22%	93%	长期股权投资	11	0	0	0
现金流量表 (百万元)	2022E	2023E	2024E	2025E	固定资产	554	760	731	707
净利润	-255	-238	-528	-534	无形资产	1	1	1	1
少数股东损益	5	0	-1	-1	非流动资产合计	622	808	779	755
营运资金变动	-6	-12	-23	22	资产总计	3932	3463	2797	2238
经营活动现金流	-402	-251	-538	-503	短期借款	207	0	0	0
投资	-279	-300	-80	-80	应付票据及应付账款	161	100	41	82
其他	-279	-300	-80	-80	其它流动负债	218	11	11	11
投资活动现金流	-646	-300	-80	-80	流动负债合计	380	111	52	93
债权募资	0	0	0	0	长期借款	29	29	29	29
股权募资	0	0	0	0	其它长期负债	185	550	102	-29
其他	-6	0	0	0	非流动负债合计	213	578	131	-1
融资活动现金流	-8	-2	-2	-2	负债总计	593	689	183	93
现金净流量	-1056	-553	-620	-584	实收资本	0.17	0.17	0.17	0.17
					普通股股东权益	3340	3102	2940	2478
					少数股东权益	-1	-1	-2	-2
					负债和所有者权益合计	3932	3790	3121	2568

资料来源: HTI

APPENDIX 1**Summary****Event.**

Keymed Biosciences released 2023H1 results with revenue of 327 mnRMB (+227%), mainly represents collaboration income from AstraZeneca. R&D expenses were 250 mnRMB (+52%) and general and administrative expenses were 82 mnRMB (+61%). The net profit was 47 mnRMB. As of June 31, 2023, the company had cash and cash equivalent of 2,979 mnRMB.

Comments.

In the blue ocean of autoimmune/inflammatory market in China, the company has a leading layout among other domestically produced drugs. We expect autoimmune/inflammatory market for biologics in China biologics to grow at a CAGR of 30% to reach 87.8 bnRMB in 2030, driven by: 1) strong willingness to pay for new indications; 2) Earlier inclusion of NRDL to accelerate volume growth; 3) Pharmaceutical companies pay more attention to investing in patient education. Various factors will realize the commercial potential of autoimmune/inflammatory drugs in the huge domestic patient pool. Keymed Biosciences possess CM310 (IL-4R α), CM326 (TSLP), CM336 (MASP-2) three clinical-stage drug candidates in the field of autoimmunity, covering atopic dermatitis, chronic sinusitis with nasal polyps, asthma, chronic obstructive pulmonary disease, seasonal allergic rhinitis, IgA nephropathy and other autoimmune diseases, and the R&D progress is among the top three domestically produced drugs.

The core product CM310 is expected to be submit NDA within 2023, and the commercialization team is being built in an orderly manner. CM310, the company's in-house developed IL-4R α monoclonal antibody, has completed phase III enrollment for the indications of moderate to severe atopic dermatitis and chronic sinusitis with nasal polyps. The phase III trial for moderate to severe atopic dermatitis has reached its primary endpoint and is currently in the follow-up stage. The company expects to submit NDA for moderate to severe atopic dermatitis and chronic sinusitis with nasal polyps to CDE in 2023 and 2024H1, respectively. As CM310 approaches the key node of NDA and subsequently the approval, the company disclosed in the recent interim report meeting that they are building their in-house commercialization team to lay a good foundation for subsequent operations.

Actively collaborating to accelerate pipeline commercialization, the global right of CLDN18.2 ADC out-licensed to AstraZeneca. Among the domestically produced drugs of the same class or the same target, the company's drug candidates have high biological activity and specificity while taking the lead the progress. All of the drug candidates are among the top 3 IND approvals in China and/or the US. The company actively accelerates pipeline R&D and commercialization through external collaborations to maximize the commercialization potential of drug candidates. In early 2023, the Company entered into a worldwide exclusive licensing agreement for the CMG901 (CLDN18.2 ADC). According to the company, AstraZeneca plans to carry out a number of registrational clinical trials worldwide and is currently in the project handover stage. In addition, the company has also reached an agreement with CSPC on the Chinese mainland rights of CM310 and CM326 (TSLP) respiratory disease related indications. Under the collaboration, CM310 has initiated key phase II/III clinical trials for moderate to severe asthma indications and CM326 has started phase II clinical trials for moderate to severe asthma. In addition, the oncology pipelines CM369 (CCR8) and CM335 (CD20*CD3) are both developed in collaboration with InnoCare and are currently in the early clinical development stage.

Earnings forecast and valuation recommendations: Considering the adjustments on CM310 NDA submission and CM326 clinical development, as well as collaboration income confirmed already, we have adjusted our profit forecast and valuation using the DCF model. We predict that the 2023-2025 revenues will be 327/159/656 mnRMB respectively (previous values: 200/117/299 mnRMB respectively). Using the DCF valuation method with a WACC of 10.0% and a sustainable growth rate of 3.0%, assuming the RMB: HKD exchange rate of 1:1.10, we have adjusted the target price to HKD 77.52/share (previous value: HKD 83.75/share) and maintained an "Outperform" rating.

Risks. risks in new drug research and development, risks in new drug approval, risks in commercializing new drugs, risks in technological iteration, and risks of sustained losses and inability to pay dividends in the short term

附录 APPENDIX

重要信息披露

本研究报告由海通国际分销，海通国际是由海通国际研究有限公司(HTIRL)，Haitong Securities India Private Limited (HSIPL)，Haitong International Japan K.K. (HTIJKK)和海通国际证券有限公司(HTISCL)的证券研究团队所组成的全球品牌，海通国际证券集团(HTISG)各成员分别在其许可的司法管辖区内从事证券活动。

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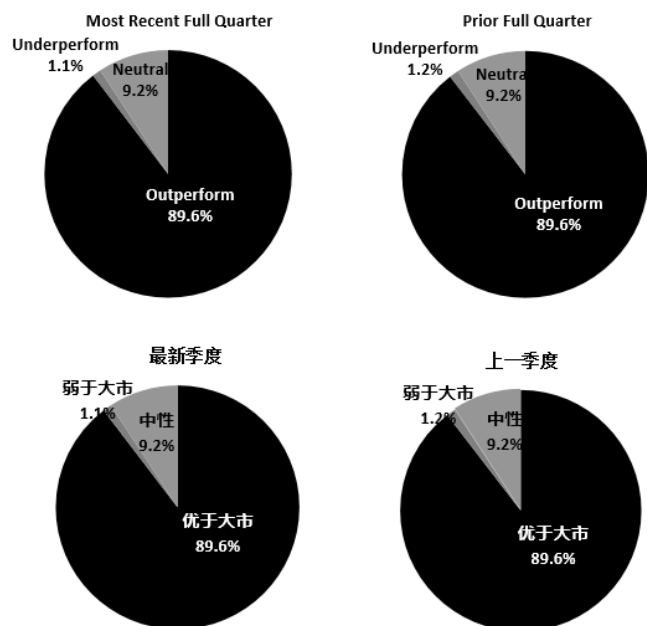
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截至 2023 年 6 月 30 日海通国际股票研究评级分布

	优于大市	中性 (持有)	弱于大市
海通国际股票研究覆盖率	89.6%	9.2%	1.1%
投资银行客户*	4.7%	5.6%	10.0%

*在每个评级类别里投资银行客户所占的百分比。

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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.

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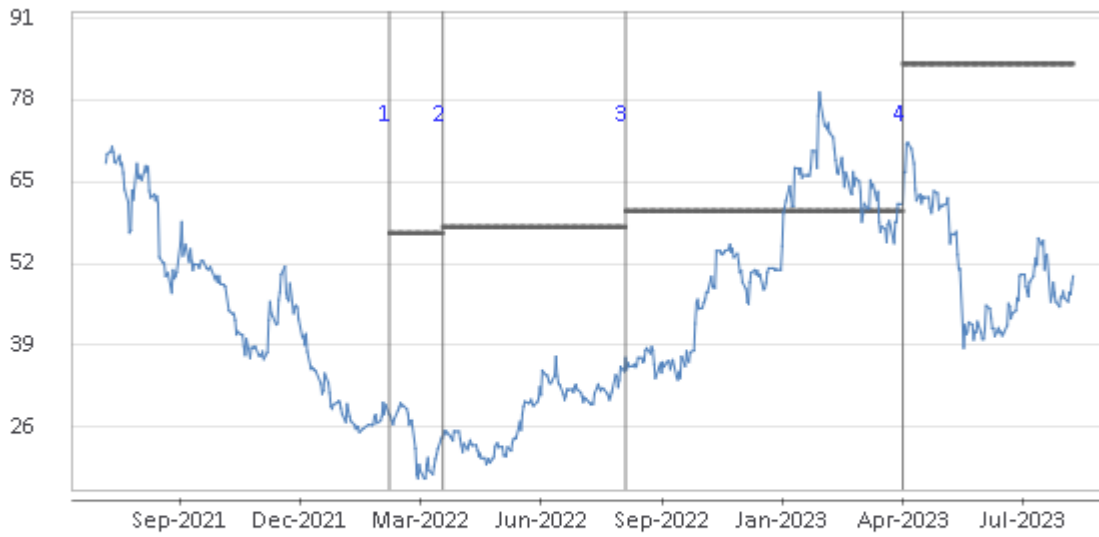
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Keymed Biosciences - 2162 HK



- 1. 21 Feb 2022 OUTPERFORM at 29.5 target 56.85.
- 2. 5 Apr 2022 OUTPERFORM at 24.3 target 57.82.
- 3. 30 Aug 2022 OUTPERFORM at 34.85 target 60.37.
- 4. 10 Apr 2023 OUTPERFORM at 61.45 target 83.75.

Source: Company data Bloomberg, HTI estimates