再鼎医药 Zai Lab (9688 HK)

艾加莫德顺利纳入医保，2024 年目标销售超过 7000 万美元
With the Inclusion of NRDL, Egfartigimod Targets 70+ mnUSD sales in 2024

观点聚焦 Investment Focus

维持优于大市 Maintain OUTPERFORM

评级	优于大市 OUTPERFORM
现价	HK$13.84
目标价	HK$66.82
HTI ESG	2.9-1.5-3.5

E-S-G: 0-5, (Please refer to the Appendix for ESG comments)

市值	HK$13.73bn / US$1.76bn
日交易额 (3 个月均值)	US$8.27mn
发行股票数目	992.09mn
自由流通股 (%)	90%
1 年股价最高最低值	HK$31.50-HK$13.84

注：现价 HK$13.84 为 2024 年 3 月 20 日收盘价

资料来源：Factset

	1mth	3mth	12mth
绝对值	-11.5%	-41.0%	-49.5%
绝对值（美元）	-11.5%	-41.2%	-49.3%
相对 MSCI China	26.1%	-2.0%	-2.8%

(US$ mn)	Dec-22A	Dec-23A	Dec-24E	Dec-25E
营业收入	215	267	367	529
(+/-)	49%	24%	38%	44%
净利润	-443	-335	-282	-149
(+/-)	n.m.	n.m.	n.m.	n.m.
全面摊薄 EPS (US$)	-0.46	-0.35	-0.29	-0.15
毛利率	65.6%	64.1%	61.5%	62.7%
净资产收益率	-42.4%	-42.0%	-52.8%	-38.5%
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

再鼎医药 2023 年产品收入 2.7 亿美元，同比+25%，按固定汇率计算同比+31%。其中，尼拉帕尼 1.7 亿美元（+16%），艾加莫德 1000 万美元，肿瘤电场治疗 4700 万美元（基本持平），瑞派替尼 1920 万美元（+29%），奥玛环素 2170 万美元（+316%）。毛利率 64.1%（-1.5pct）；研发费用 2.7 亿美元（-7%）；销售及管理费用 2.8 亿美元，销售及管理费用率 106%（-14pct）。净亏损-3.4 亿美元，较 2022 年同期净亏损减少 1.1 亿美元。截至 2023 年 12 月 31 日，公司在手现金及现金等价物、短期投资、受限制现金总计 8.1 亿美元。

点评

艾加莫德顺利纳入医保，公司预计 2024 年销售超过 7000 万美元。2023 年 6 月，艾加莫德在中国获批用于治疗 AChR 抗体阳性的全身型重症肌无力（gMG），同年 9 月在中国正式商业化；据公司披露，至 2023 年底，约有 1000 例患者用药。随艾加莫德纳入医保目录并执行新价格（约 800 美元/针；按临床研究方案用药，相当于年治疗费用 3.2 万美元），2024 年 1 月，约 1000 例新患者处方用药，与 2023 年 4 个商业化月份的新患人数总和相当。中国现存超过 17 万 gMG 患者，其中相当一部分患者存在残留症状或治疗不充分。公司计划扩张商业化团队制 150 人，目标医院由 200 家拓展至 1000 家，以触及＞80%的潜在用药患者；公司预计，2024 年收入将超过 7000 万美元。目前，艾加莫德 gMG 适应症的皮下剂型的上市申请已获得受理，有望年内获批并为患者提供更多治疗选择。

公司目标在 2028 年实现超过 15 款产品上市，收入超过 20 亿美元。2023 年，公司已有 5 款产品获批上市，收入 2.7 亿美元。目前，公司有 3 款产品处于 NDA 阶段，分别为艾加莫德皮下注射剂型（gMG）、瑞普替尼（ROS1+ NSCLC）、舒巴坦+度洛巴坦（鲍曼不动杆菌感染），均有望在 2024 年内获批上市。公司计划在 2024 年递交 4 项新药或新适应症的上市申请，包括 Adagrasib（KRAS G12C+ 2L+NSCLC）、TF ADC（2L+宫颈癌）、艾加莫德（CIPD）、肿瘤电场治疗（2L+ NSCLC），并预计 KarXT（精神分裂症）、贝马利珠单抗（一线胃癌）在 2025 年获批。我们认为，上述产品及适应症的上市及商业化有望支持公司未来 3~5 年增长，推动公司向 2028 年 20 亿美元收入目标迈进。

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净亏损收窄至-3.4 亿美元，向 2025 年底实现公司整体盈利的目标迈进。2023 年公司毛利率 64.1%（-1.4pct）。销售及管理费用 2.8 亿美元（+9%），销售及管理费用率 106%（-14pct），费用金额增加主要与艾加莫德上市推广有关；研发费用 2.7 亿美元（-7%），费用金额减少主要与授权合作的首付款里程碑付款减少有关；整体费用控制合理。我们认为，基于现有商业化平台，销售及行政费用将保持合理增长；基于有规划的中后期管线开发及合作付款安排，研发费用有可能维持在可控范围。在 8.1 亿美元现金储备的支持下，随 2023-25 年的新产品及适应症获批上市并放量，我们认为公司正在向整体盈利目标迈进。

盈利预测及估值

根据公司已上市产品的销售表现、医保目录价格调整、在研管线调整，我们调整 2024-25 年收入预测为 3.7/5.3 亿美元，同比+38/44%（2024E 前值：4.2 百万美元）；结合收入预测调整，并根据艾加莫德产能安排、新产品上市推广投入增加、管线开发计划，我们调整 2024-25E 净利润预测为-2.8/-1.5 亿美元（2024E 前值：-2.4 亿美元）。我们根据 DCF 模型对公司进行估值，采用 FY2025-31 现金流进行测算，WACC 为 9.9%，永续增长率 2.0%，假设美元兑港元汇率 1:7.82，对应目标价为 66.82 HKD/股（前值：70.73 HKD/股），维持优于大市评级。

风险

政策变动风险，产品研发风险，销售放量不及预期风险。

Fig 1. 公司肿瘤管线 2024 年潜在里程碑

	Key Progress in 2023 / 2024 YTD	Key Milestones in 2024
Bemarituzumab (*1L FGFR2b+ GC*)	✓ Ph3 FORTITUDE-101, continues to enroll patients ✓ Joined Ph3 FORTITUDE-102 study in Greater China	• Accelerate the enrollment of both studies
TTFields	✓ *2L+ NSCLC*: FDA filed premarket approval application (PMA)	• *2L+ NSCLC*: Potential China submission • *Other indications*: Pivotal readouts in 1L brain metastases from NSCLC (1Q'24) and in 1L pancreatic cancer (4Q'24)
Repotrectinib (*ROS1+ NSCLC*)	✓ Updated results from the registrational TRIDENT-1 study ✓ NDA acceptance with priority review in China	• Potential approval and launch in China
Adagrasib	✓ *2L+ NSCLC*: Two-year follow-up data from KRYSTAL-1 study ✓ *3L+ CRC*: FDA sNDA acceptance with a PDUFA date of Jun 21st, 2024	• *2L+ NSCLC*: Clinical data readout of Ph3 KRYSTAL-12 study and China submission
TIVDAK (*2L+ CC*)	✓ Positive interim analyses of the Ph3 innovaTV-301 study	• Potential China submission
ZL-1310 (DLL3 ADC, *SCLC*)	✓ Initiated global Ph1 study	• Present the preclinical data at ELCC 2023 • Potential early clinical data depending on dose escalation

Source: 公司年报演示材料，HTI

Fig 2. 公司神经、自免、抗感染管线 2024 年潜在里程碑

	Key Progress in 2023 / 2024 YTD	Key Milestones in 2024
Efgartigimod	✓ *CIDP*: Positive data readout of ADHERE study; FDA acceptance of sBLA with a PDUFA date of Jun 21st, 2024 ✓ *gMG (SC)*: sBLA acceptance in China	• *CIDP*: Potential China submission in 1H'24 • *gMG (SC)*: Potential sBLA approval and launch in China • *TED*: Initiate and join the global registrational study in China in 2H'24
KarXT	✓ *Schizophrenia*: FDA acceptance of Karuna NDA with a PDUFA date of Sept 26th, 2024	• *Schizophrenia*: Complete enrollment in China bridging study in 4Q'24 • *ADP*: Join the global Ph3 ADEPT-2 and ADEPT-3 studies in China in mid-24
SUL-DUR (*ABC*)	✓ NDA acceptance with priority review in China	• Potential approval and launch in China
ZL-1102 (IL-17 Humabody, *CPP*)	✓ In the final stage of preparation for a global Ph2 dose-finding trial	• Initiate the global Ph2 study in mid-24

Source: 公司年报演示材料，HTI

Table 1 DCF 估值法

USD mn	FY23	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
	2023	2024	2025	2026	2027	2028	2029	2030	2031
Time Factor (fraction of year to next FY end)			1.0	2.0	3.0	4.0	5.0	6.0	7.0
Sales	**266.7**	**367.5**	**528.7**	**766.1**	**1,099.8**	**1,608.7**	**2,159.4**	**2,714.2**	**3,305.7**
... Growth	*24.0%*	*37.8%*	*43.9%*	*44.9%*	*43.6%*	*46.3%*	*34.2%*	*25.7%*	*21.8%*
Gross Profit	170.9	226.0	331.5	495.7	717.1	1,056.9	1,429.5	1,804.9	2,208.2
... GP Margin	*64.1%*	*61.5%*	*62.7%*	*64.7%*	*65.2%*	*65.7%*	*66.2%*	*66.5%*	*66.8%*
SG&A	-281.6	-301.3	-316.4	-332.2	-348.8	-366.3	-384.6	-403.8	-424.0
… SG&A Margin	*105.6%*	*82.0%*	*59.8%*	*43.4%*	*31.7%*	*22.8%*	*17.8%*	*14.9%*	*12.8%*
Depreciation & Amortisation	9.0	8.9	9.5	10.9	12.6	14.6	17.9	22.4	27.8
EBIT	**-374.4**	**-322.0**	**-188.4**	**-35.9**	**159.3**	**471.7**	**815.4**	**1160.5**	**1531.9**
Add: Amortisation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITA	**-374.4**	**-322.0**	**-188.4**	**-35.9**	**159.3**	**471.7**	**815.4**	**1160.5**	**1531.9**
… Margin	*-140.4%*	*-87.6%*	*-35.6%*	*-4.7%*	*14.5%*	*29.3%*	*37.8%*	*42.8%*	*46.3%*
… Growth									
Add: Depreciation	9.0	8.9	9.5	10.9	12.6	14.6	17.9	22.4	27.8
EBITDA	**-365.4**	**-313.1**	**-178.9**	**-25.0**	**171.9**	**486.3**	**833.3**	**1,182.9**	**1,559.7**
… Margin	*-137.0%*	*-85.2%*	*-33.8%*	*-3.3%*	*15.6%*	*30.2%*	*38.6%*	*43.6%*	*47.2%*
Less: Tax	0.0	0.0	0.0	-0.5	-23.9	-61.4	-102.6	-144.0	-184.5
Less: Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Less: Increase of Working Capi	-17.2	-36.7	-52.9	-61.3	-77.0	-96.5	-108.0	-135.7	-165.3
Less: Capex	-7.2	-9.9	-15.9	-23.0	-22.0	-32.2	-43.2	-54.3	-66.1
... Capex:Depreciation	*0.8x*	*1.1x*	*1.7x*	*2.1x*	*1.7x*	*2.2x*	*2.4x*	*2.4x*	*2.4x*
Less: Acquisitions	-134.0	-134.0	-134.0	-134.0	-134.0	-134.0	-134.0	-134.0	-134.0
Free Cash Flow	**-523.8**	**-493.8**	**-381.6**	**-243.8**	**-85.0**	**162.2**	**445.5**	**714.8**	**1,009.8**
... FCF Growth	*-21.7%*	*-5.7%*	*-22.7%*	*-36.1%*	*-65.1%*	*-291.0%*	*174.6%*	*60.4%*	*41.3%*
PV of FCF	**-523.8**	**-493.8**	**-347.1**	**-201.7**	**-63.9**	**111.1**	**277.5**	**405.1**	**520.5**

WACC		**DCF Valuation**	
Risk Free Rate	1.5%	Sum of PV of FCF	701.4
Market Risk Premium	10.0%	PV of Terminal Value	6,694.9
Equity Beta	1.05	Enterprise Value	7,396.2
Cost of Equity	12.0%	Add: Net Cash 23FY	790.5
Cost of Debt (Pre-tax)	6.0%	Equity Value	8,186.7
Cost of Debt (After tax)	5.1%	No. of Ord shares (m), fully diluted	958.1
Target Debt weight	30.0%		
Target Equity weight	70.0%	Value per Share, USD	8.55
Tax Rate	15.0%	FX: USD/HKD	7.82

WACC	**9.9%**	**Terminal Growth**	**2.0%**	**Value per Share, HKD**	**$66.82**

资料来源： HTI

Table 2 财务报表

Key ratios	2022A	2023A	2024E	2025E
EPS(USD)	-0.46	-0.35	-0.29	-0.15
BVPS(USD)	1.09	0.82	0.55	0.40
Operating cash flow per share(USD)	-0.38	-0.21	-0.32	-0.20
DPS(USD)	0.00	0.00	0.00	0.00
P/E	(3.83)	(5.11)	(6.06)	(11.51)
P/B	1.62	2.15	3.20	4.43
P/S	8.17	6.58	4.78	3.32
EV/EBITDA	(4)	(5)	(6)	(10)
Dividned yield	0%	0%	0%	0%
Gross margin	66%	64%	62%	63%
Net margin	-206%	-125%	-77%	-28%
ROE	-42%	-42%	-53%	-38%
ROA	-36%	-32%	-38%	-24%
ROIC	-20%	-18%	-24%	-17%
Revenue growth	49%	24%	38%	44%
EBIT growth	-35%	-18%	-14%	-42%
Net profit growth	-37%	-25%	-16%	-47%
Asset/liability ratio	699%	431%	361%	264%
Liquidlity ratio	804%	463%	381%	260%
Quick ratio	781%	441%	342%	213%
Cash ratio	721%	389%	279%	129%
AR days	82	89	89	89
Inventory days	156	171	171	171
Total asset turnover	18%	26%	50%	85%
Fixed asset turnover	224%	276%	366%	495%
Cash flow (USD mn)	**2022A**	**2023A**	**2024E**	**2025E**
Net profit	-443	-335	-282	-149
Minority interests	0	0	0	0
Non-cash expenses	8	9	9	9
Non operating income	-15	-40	-40	-40
Change in working capital	-66	17	37	53
Operating cash flow	**-368**	**-198**	**-310**	**-192**
Assets	-25	-7	-10	-16
Investment	-260	-134	-134	-134
Others	705	130	130	130
Investment cash flow	**420**	**-11**	**-14**	**-19**
Increase in debts	0	0	0	0
Proceeds from issue of shares	6	2	0	0
Others	-8	-9	0	0
Financing cash flow	**-2**	**-6**	**0**	**0**
Net cash inflow	**51**	**-215**	**-324**	**-211**

IS (USD mn)	2022A	2023A	2024E	2025E
Revenue	**215**	**267**	**367**	**529**
COGS	74	96	141	197
GPM (%)	66%	64%	62%	63%
Business tax and surcharges	0	0	0	0
Tax rate (%)	0.0%	0.0%	0.0%	0.0%
Operating expense	259	282	301	316
Operating expense ratio (%)	120.4%	105.6%	82.0%	59.8%
Administrative expense				
Administrative expense ratio (%)				
EBIT	-458	-374	-322	-188
Financing expense	0	0	0	0
Financing expense ratio (%)	0.0%	0.0%	0.0%	0.0%
Assets impairment loss				
Investment profit	14	40	40	40
Operating profit	**-404**	**-367**	**-314**	**-181**
Exceptional income-net	0	0	0	0
Pre-tax profit	**-443**	**-335**	**-282**	**-149**
EBITDA	-450	-365	-313	-179
Taxation	0	0	0	0
Tax rate (%)	0	0	0	0
Minority interests	0	0	0	0
Net income to ord equity	**-443**	**-335**	**-282**	**-149**
Financial statement (USD mn)	**2022A**	**2023A**	**2024E**	**2025E**
Cash	1008	790	467	256
Account receivable	49	65	90	130
Inventory	32	45	66	92
Other current assets	36	39	16	37
Total current assets	1124	940	639	515
Long-term equity investment				
Tangible assets	84	78	82	88
Construction in progress				
Intangible assets	2	13	13	13
Total non-current assets	96	97	101	107
Total assets	**1220**	**1036**	**739**	**621**
Short-term debts	7	7	7	7
Account payable	66	113	78	108
Prepayments	0	0	0	0
Other current liabilities	67	83	83	83
Total current liabilities	140	203	168	198
Long-term debts	0	0	0	0
Other long-term liabilities	35	37	37	37
Total non-current liabilities	35	37	37	37
Total liabilities	**175**	**240**	**205**	**235**
Common stocks	1046	796	535	386
Retain earnings reserves	-1836	-2158	-2441	-2589
Minority interests	0	0	0	0
Total liabilities and equities	**1220**	**1036**	**739**	**621**

资料来源：WIND（20240320close），HTI

APPENDIX 1

Summary

Event. Zai Lab's 2023 product revenue was $267 million, yoy +25% and +31% at CER. Of this amount, ZEJULA was $169 million (+16%), VYVGART was US$10 million, OPTUNE $47 million (basically flat), QINLOCK was $19 million (+29%), and NUZYRA was $22 million (+316%). Gross margin was 64.1% (-1.5 pct), R&D expenses were $266 million (-7%), and SG&A expenses were $282 million, with an SG&A epxpense ratio of 106% (-14 pct). Net loss was -$335 million, a decrease of $109 million from the net loss for the same period in 2022. As of December 31, 2023, the company had cash position of $808 million.

Comment.

VYVGART was successfully included in the NRDL, and the company expects to sell more than $70 million in 2024. In June 2023, VYVGART was approved in China for the treatment of AChR antibody-positive generalized myasthenia gravis (gMG), and launched in China in September of the same year. According to the company's disclosure, by the end of 2023, nearly 1,000 patients treated. With the inclusion of VYVGART in the NRDL and the implementation of the new price (about $800 per vial; According to the clinical study protocol, equivalent to an annual cost of $32,000), in January 2024, about 1,000 new patients were treated, which is equivalent to the total number of new patients in the four months of commercialization in 2023. There are more than 170,000 gMG patients in China, with a significant number have residual symptoms or inadequate treatment. The company plans to expand the commercial team to 150 people, and expand the target hospitals from 200 to 1,000 to reach >80% of potentia. The company expects revenue of VYVGART to exceed $70 million in 2024. At present, the NDA for the subcutaneous dosage form of efgartigimod gMG indication has been accepted, and it is expected to be approved within the year and provide patients with more treatment options.

The company aims to launch more than 15 products with revenues of more than $2 billion by 2028. In 2023, the company has 5 approved products, with revenue of $267 million. At present, the company has 3 products in the NDA stage, namely efgartigimod subcutaneous form (gMG), repotrectinib (ROS1+ NSCLC), SUL+DUL (acinetobacter baumannii-calcoaceticus complex), all of which are expected to be approved for marketing in 2024. The company plans to submit 4 NDA/sNDA in 2024, including Adagrasib (KRAS G12C+ 2L+NSCLC), TF ADC (2L+ cervical cancer), efgartigimod (CIPD), Tumor Treating Fields (2L+ NSCLC), and expects KarXT (schizophrenia) and bemarituzumab (first-line gastric cancer) to be approved in 2025. We believe that the launch and commercialization of the above products and indications are expected to support the company's growth in the next 3~5 years and drive the company towards the revenue target of $2 billion in 2028.

Net loss narrowed to -$335 million, moving towards the company's goal of achieving overall profitability by the end of 2025. In 2023, the company's gross profit margin was 64.1% (-1.4pct). SG&A expenses of $282 million (+9%), with a SG&A expense ratio of 106% (-14pct), with the increase in the amount of expenses mainly related to the launch of VYVGART, and R&D expenses of $266 million (-7%), mainly related to the decreased upfront and milestone payments for license and collaboration agreements. The overall expense was reasonable. We believe that based on the existing commercialization platform, the SG&A expenses will maintain reasonable growth, and the R&D expenses are likely to remain within a manageable range based on the planned mid-to-late stage pipeline development and collaboration payment arrangements. Supported by $808 million cash position, we believe the company is on track to achieve its overall profitability target with new product and indication approvals and ramp-up in 2023-25.

Earnings forecasts and valuations. Based on the sales performance of the company's marketed products, the price adjustment of the NRDL, and the adjustment of the pipeline under development, we adjust the revenue forecast for 2024-25 to $367/529 million, +38/44% yoy (previous value in 2024E: $418 million), and we adjust the net profit forecast for 2024-25E to -$282/-149 million (previous value 2024E: -$243 million). We value the company according to the DCF model, using FY2024-31 cash flow to calculate, WACC of 9.9%, perpetual growth rate of 2.0%, assuming USD/HKD exchange rate of 1:7.82, corresponding to a target price of 66.82 HKD/share (previous value: 70.73 HKD/share), maintaining an “Outperform” rating.

Risks. Risk of clinical development failure, risk of government regulation, risk of drug approval failure.

Landscape

Title

Source: HTI

APPENDIX 2

ESG Comments

Environmental:

Contract with global top tier CDMO to be eco-friendly

Social:

Drugs aiming to improve clinical benefit for patients

Governance:

adequate corporate governace

附录 APPENDIX

重要信息披露

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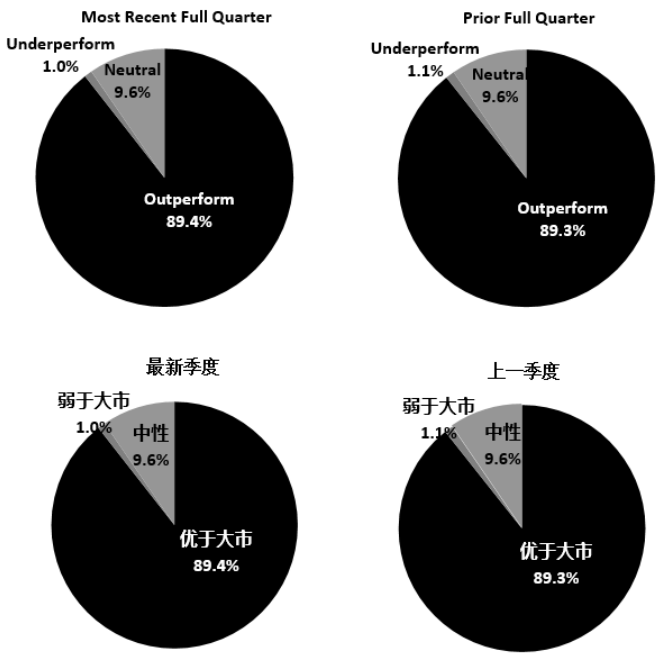

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各地股票基准指数：日本 –TOPIX, 韩国 –KOSPI, 台湾 –TAIEX, 印度 –Nifty100; 其他所有中国概念股 –MSCI China.

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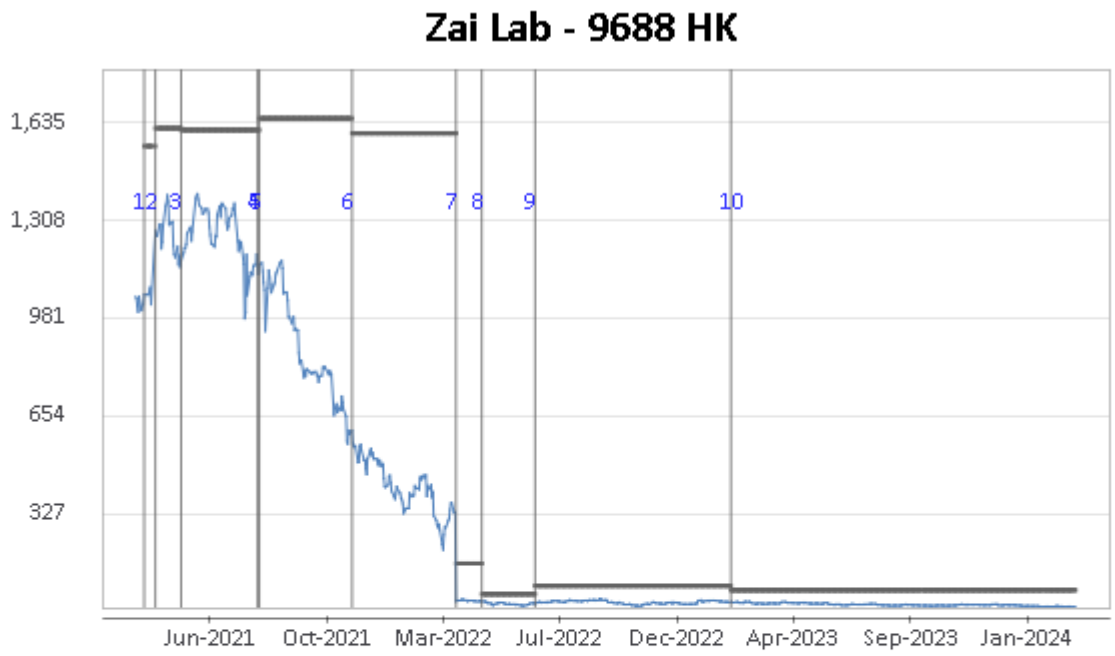

1. 2 Apr 2021 OUTPERFORM at 1029.0 target 1557.0.
2. 14 Apr 2021 OUTPERFORM at 1027.0 target 1617.0.
3. 14 May 2021 OUTPERFORM at 1160.0 target 1611.0.
4. 11 Aug 2021 OUTPERFORM at 1195.0 target 1611.0.
5. 13 Aug 2021 OUTPERFORM at 1195.0 target 1650.0.
6. 29 Nov 2021 OUTPERFORM at 604.5 target 1600.0.
7. 29 Apr 2022 OUTPERFORM at 35.05 target 57.48.
8. 30 Jun 2022 OUTPERFORM at 26.6 target 85.23.
9. 13 Feb 2023 OUTPERFORM at 30.05 target 70.73.

10-for-1 split implemented on 30 Mar 2022

Source: Company data Bloomberg, HTI estimates