再鼎医药 Zai Lab (9688 HK)

2024 年艾加莫德指引上调至 8000 万美元，三款产品在中国获批
Efgartigimod Guidance Raised to 80mn USD, 3 Products Approved in China

观点聚焦 Investment Focus

维持优于大市 Maintain OUTPERFORM

评级	优于大市 OUTPERFORM
现价	HK$12.50
目标价	HK$65.76
HTI ESG	2.9-1.5-4.0

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

市值	HK$12.45bn / US$1.60bn
日交易额 (3 个月均值)	US$10.10mn
发行股票数目	996.09mn
自由流通股 (%)	90%
1 年股价最高最低值	HK$23.45-HK$10.62

注：现价 HK$12.50 为 2024 年 08 月 13 日收盘价

资料来源：Factset

	1mth	3mth	12mth
绝对值	-10.7%	-22.8%	-38.7%
绝对值（美元）	-10.5%	-22.6%	-38.5%
相对 MSCI China	-5.2%	-13.1%	-29.4%

US$ mn	Dec-22A	Dec-23A	Dec-24E	Dec-25E
Revenue	215	267	387	518
Revenue (+/-)	49%	24%	45%	34%
Net profit	-443	-335	-289	-159
Net profit (+/-)	n.m.	n.m.	n.m.	n.m.
Diluted EPS (US$)	-0.46	-0.35	-0.30	-0.16
GPM	65.6%	64.1%	60.0%	61.2%
ROE	-42.4%	-42.0%	-54.7%	-43.1%
P/E	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

再鼎医药公布 2024Q2 业绩：产品收入净额 1.0 亿美元（+45%），其中艾加莫德 2320 万美元。毛利率 64.9%（-0.6pct）；R&D 费用 6163 万美元（-19.6%），R&D 费用占产品收入 61.6%（-49.8pct）；SG&A 费用 7971 万美元（+17.4%），SG&A 费用占产品收入 79.6%（-19.0pct）。净亏损 8028 万美元，去年同期为 1.2 亿美元。截至 2024 年 6 月 30 日，公司在手现金、现金等价物、受限制现金 7.3 亿美元。艾加莫德销售超预期，全年指引上调至 8000 万美元（前值：7000 万美元）。

点评

艾加莫德医保内销售持续增长，全年指引上调至 8000 万美元。2024Q2，艾加莫德销售 2320 万美元，环比 2024Q1 增长 76%（2024Q1：1316 万美元）。据业绩会披露，截至 2024Q2，医院覆盖已实现 70%进院目标，~1500 名医生有处方经验；新患方面，2024Q2 新患约 3300 人，结合 2024Q1，我们换算进入医保后保持约 1000+新患/月。此外，更多的患者已经开始第二、三周期的治疗。基于上半年良好的销售表现，公司上调全年指引至 8000 万美元（前值：7000 万美元）。

艾加莫德 CIPD 适应症申报上市，更多适应症拓展挖掘潜力。艾加莫德皮下剂型的 CIDP 适应症已于 2024 年 5 月在中国递交 sBLA，公司预计有望在 2025 年中国获批上市。甲状腺眼病、血清阴性 gMG 及眼肌型 MG 有望在 2024H2-2025 年初陆续加入全球注册性临床研究。此外，艾加莫德 gMG 适应症的皮下剂型在中国已经获批上市。我们认为适应症的拓展有望进一步释放艾加莫德的商业化潜力，不同的剂型选择可能为患者提供用药的灵活性并为产品提高竞争壁垒。

潜在重磅产品有望陆续上市，为公司未来 3-5 年增长提供动能。SUL-DUR（一种针对鲍曼不动杆菌的抗生素）已于 2024 年 5 月在中国获批；公司预期产品峰值潜力 5-10 亿美元。KarXT 中国桥接研究的关键临床有望在 2024H2 读出，助力潜在新药上市申请；阿尔兹海默病引起的精神障碍适应症加入全球 III 期临床研究；公司预期产品峰值潜力>10 亿美元。靶向 FGFR2b 的 Bemarituzumab 的 2 项 III 期研究正在进行中，其中 FORTITUDE-101 研究完成受试者入组，FORTITUDE-102 研究入组进行中，公司预期产品峰值潜力>10 亿美元。我们认为，在艾加莫德以及上市 3 款潜在重磅产品的销售拉动下，公司 2023-2028 年有望实现 CAGR~50%的收入增长。

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费用不断优化，重申 2025 年底公司整体盈亏平衡目标。2024Q2，公司毛利率 64.9%（-0.6pct），我们预期随艾加莫德产能释放，毛利率可能改善。三费精细化管控，随收入增长，费用率进一步下降：2024Q2，R&D 费用 6163 万美元（-19.6%），R&D 费用占产品收入 61.6%（-49.8pct）；SG&A 费用 7971 万美元（+17.4%），SG&A 费用占产品收入 79.6%（-19.0pct），与艾加莫德销售人员及费用增加有关。2024Q2，公司净亏损 8028 万美元，去年同期为 1.2 亿美元。在收入快速增长、费用优化的条件下，公司重申 2025 年底整体盈亏平衡的目标。

进一步扩充、推进全球权益管线的研发。2024 年 7 月，公司与麦科思达成全球许可协议，获得 ROR1 ADC 的全球权益，扩充管线。根据业绩会，公司目前仍有多个未披露的处于临床前阶段的管线，目标每年至少递交 1 个全球新药临床研究申请。全球权益管线中：1）IL-17A 目前已经开展一项针对中轻度慢性斑块状银屑病的全球 II 期研究；2）DLL3 ADC 预计在 2024 年底-2025 年初公布针对 2L+ SCLC 的剂量递增数据；3）CCR8 预计在 2024 ESMO 公布 I 期 PK/PD 分析。

盈利预测及估值

根据艾加莫德及爱普盾二季度销售表现，我们调整 2024-25 年收入预测为 3.87/5.18 亿美元（前值：3.81/5.18 亿美元），同比 +45/34%；调整 2024-25 净利润预测为-2.89/-1.59 亿美元（前值：-2.88/-1.59 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 1:7.83，对应目标价为 65.76HKD/股（前值：67.51 HKD/股，下调 2.6%），维持优于大市评级。

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；持续亏损及短期内无法现金分红风险。

Table 1 DCF 估值

USD mn	FY23	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
	2023	2024	2025	2026	2027	2028	2029	2030	2031
Forecast Year			1	2.0	3.0	4.0	5.0	6.0	7.0
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**	**386.7**	**518.0**	**758.8**	**1,097.0**	**1,621.7**	**2,197.8**	**2,785.7**	**3,418.1**
... Growth	*24.0%*	*45.0%*	*34.0%*	*46.5%*	*44.6%*	*47.8%*	*35.5%*	*26.7%*	*22.7%*
Gross Profit	170.9	232.0	317.0	479.6	698.8	1,041.1	1,422.0	1,810.7	2,232.0
... GP Margin	*64.1%*	*60.0%*	*61.2%*	*63.2%*	*63.7%*	*64.2%*	*64.7%*	*65.0%*	*65.3%*
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%*	*77.9%*	*61.1%*	*43.8%*	*31.8%*	*22.6%*	*17.5%*	*14.5%*	*12.4%*
Depreciation & Amortisation	9.0	9.0	9.5	10.9	12.6	14.6	18.0	22.6	28.3
EBIT	**-374.4**	**-328.5**	**-198.9**	**-50.2**	**143.0**	**457.9**	**810.0**	**1168.5**	**1558.1**
Add: Amortisation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITA	**-374.4**	**-328.5**	**-198.9**	**-50.2**	**143.0**	**457.9**	**810.0**	**1168.5**	**1558.1**
... Margin	*-140.4%*	*-85.0%*	*-38.4%*	*-6.6%*	*13.0%*	*28.2%*	*36.9%*	*41.9%*	*45.6%*
... Growth									
Add: Depreciation	9.0	9.0	9.5	10.9	12.6	14.6	18.0	22.6	28.3
EBITDA	**-365.4**	**-319.5**	**-189.3**	**-39.3**	**155.5**	**472.5**	**828.0**	**1,191.1**	**1,586.4**
... Margin	*-137.0%*	*-82.6%*	*-36.6%*	*-5.2%*	*14.2%*	*29.1%*	*37.7%*	*42.8%*	*46.4%*
Less: Tax	0.0	0.0	0.0	1.2	-21.9	-59.7	-102.0	-145.0	-187.7
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	-38.7	-51.8	-60.7	-76.8	-97.3	-109.9	-139.3	-170.9
Less: Capex	-7.2	-10.5	-15.5	-22.8	-21.9	-32.4	-44.0	-55.7	-68.4
... Capex:Depreciation	*0.8x*	*1.2x*	*1.6x*	*2.1x*	*1.7x*	*2.2x*	*2.4x*	*2.5x*	*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**	**-502.6**	**-390.7**	**-255.5**	**-99.1**	**149.1**	**438.2**	**717.1**	**1,025.4**
... FCF Growth	*-21.7%*	*-4.0%*	*-22.3%*	*-34.6%*	*-61.2%*	*-250.4%*	*194.0%*	*63.7%*	*43.0%*
PV of FCF	**-523.8**	**-502.6**	**-355.4**	**-211.4**	**-74.6**	**102.1**	**272.9**	**406.3**	**528.5**

WACC		**DCF Valuation**	
Risk Free Rate	1.5%	Sum of PV of FCF	668.4
Market Risk Premium	10.0%	PV of Terminal Value	6,798.4
Equity Beta	1.05	Enterprise Value	7,466.9
Cost of Equity	12.0%	Add: Net Cash 24H1	730.0
Cost of Debt (Pre-tax)	6.0%	Equity Value	8,196.9
Cost of Debt (After tax)	5.1%	No. of Ord shares (m), fully diluted	975.9
Target Debt weight	30.0%		
Target Equity weight	70.0%	Value per Share, USD	8.40
Tax Rate	15.0%	FX: USD/HKD	7.83

WACC	**9.9%**	**Terminal Growth**	**2.0%**	**Value per Share, HKD**	**$65.76**

资料来源：HTI

Table 2 财务报表

Key ratios	2022A	2023A	2024E	2025E
EPS(USD)	-0.46	-0.35	-0.30	-0.16
BVPS(USD)	1.09	0.82	0.54	0.38
Operating cash flow per share(USD	-0.38	-0.21	-0.33	-0.21
DPS(USD)	0.00	0.00	0.00	0.00
P/E	(3.43)	(4.58)	(5.36)	(9.73)
P/B	1.45	1.93	2.93	4.19
P/S	7.35	5.92	4.09	3.05
EV/EBITDA	(4)	(4)	(5)	(8)
Dividned yield	0%	0%	0%	0%
Gross margin	66%	64%	60%	61%
Net margin	-206%	-125%	-75%	-31%
ROE	-42%	-42%	-55%	-43%
ROA	-36%	-32%	-39%	-26%
ROIC	-20%	-18%	-24%	-19%
Revenue growth	49%	24%	45%	34%
EBIT growth	-35%	-18%	-12%	-39%
Net profit growth	-37%	-25%	-14%	-45%
Asset/liability ratio	699%	431%	349%	256%
Liquidlity ratio	804%	463%	366%	249%
Quick ratio	781%	441%	324%	203%
Cash ratio	721%	389%	262%	119%
AR days	82	89	89	89
Inventory days	156	171	171	171
Total asset turnover	18%	26%	52%	85%
Fixed asset turnover	224%	276%	383%	484%

Cash flow (USD mn)	2022A	2023A	2024E	2025E
Net profit	-443	-335	-289	-159
Minority interests	0	0	0	0
Non-cash expenses	8	9	9	10
Non operating income	-15	-40	-40	-40
Change in working capital	-66	17	39	52
Operating cash flow	**-368**	**-198**	**-318**	**-201**
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**	**-332**	**-220**

IS (USD mn)	2022A	2023A	2024E	2025E
Revenue	**215**	**267**	**387**	**518**
COGS	74	96	155	201
GPM (%)	66%	64%	60%	61%
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%	77.9%	61.1%
Administrative expense				
Administrative expense ratio (%)				
EBIT	-458	-374	-328	-199
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**	**-321**	**-191**
Exceptional income-net	0	0	0	0
Pre-tax profit	**-443**	**-335**	**-289**	**-159**
EBITDA	-450	-365	-320	-189
Taxation	0	0	0	0
Tax rate (%)	0	0	0	0
Minority interests	0	0	0	0
Net income to ord equity	**-443**	**-335**	**-289**	**-159**

Financial statement (USD mn)	2022A	2023A	2024E	2025E
Cash	1008	790	458	238
Account receivable	49	65	95	127
Inventory	32	45	72	94
Other current assets	36	39	14	41
Total current assets	1124	940	639	499
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**	**740**	**606**
Short-term debts	7	7	7	7
Account payable	66	113	85	110
Prepayments	0	0	0	0
Other current liabilities	67	83	83	83
Total current liabilities	140	203	175	200
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**	**212**	**237**
Common stocks	1046	796	528	369
Retain earnings reserves	-1836	-2158	-2447	-2606
Minority interests	0	0	0	0
Total liabilities and equities	**1220**	**1036**	**740**	**606**

资料来源：WIND(20240812 close), HTI

APPENDIX 1

Summary

Event. Zai Lab Announces 2024Q2 Results with product revenue of $100 million (+45%), of which VYVGART is $23.2 million. Gross margin was 64.9% (-0.6 pct), R&D expenses were $61.63 million (-19.6%), R&D expenses accounted for 61.6% (-49.8 pct) of product revenue, SG&A expenses were $79.71 million (+17.4%), and SG&A expenses accounted for 79.6% (-19.0 pct) of product revenue. Net loss was $80.28 million, compared to $120 million in the same period last year. As of June 30, 2024, the company had $730 million in cash, cash equivalents and restricted cash on hand. VYVGART sales beat expectations and raised its full-year guidance to $80 million (prior: $70 million).

Comments.

VYVGART sales continued to grow after NRDL listing, raising its full-year guidance to $80 million. In 2024Q2, VYVGART recorded sales of $23.2 million, an increase of 76% from 2024Q1 (2024Q1: $13.16 million). According to the conference call, as of 2024Q2, the hospital coverage has achieved the target of 70% listing, and ~1,500 doctors have prescription experience; In terms of new patients, there will be about 3,300 new patients in 2024Q2, and combined with 2024Q1, we estimate VYVGART maintained about 1,000+ new patients per month after NRDL listing in 2024H1. In addition, more patients have already started the second or third cycle of treatment. Based on the strong sales performance in 2024H1, the company raised its full-year guidance to $80 million (prior: $70 million).

VYVGART-hytrulo's CIPD indication has submitted sBLA, and more indications were expanded and tapped potential. The CIDP indication for the subcutaneous dosage form of VYVGART has submitted sBLA in China in May 2024 and the company expects to be approved for marketing in China in 2025. TED, seronegative gMG and ocular MG are expected to join global registrational trials from 2024H2 to early 2025. In addition, the subcutaneous dosage form of VYVGART for the indication of gMG has been approved for marketing in China. We believe that the expansion of the indication is expected to further unlock the commercialization potential of VYVGART, and the choice of different dosage forms may provide patients with drug flexibility and raise the competitive barrier for the product.

Potential blockbuster products are expected to be launched one after another, providing momentum for the company's growth in the next 3-5 years. SUL-DUR, an antibiotic against Acinetobacter baumannii, was approved in China in May 2024; The company expects a peak product potential of $0.5 billion to $1 billion. The pivotal bridging study of KarXT in China is expected to be read out in 2024H2, which will help potential NDA; The indication of ADP has joined global phase III clinical trial; The company expects the peak potential of its products to > $1 billion. Two Phase III studies of bemarituzumab targeting FGFR2b are underway, with the FORTITUDE-101 study completing enrollment and the FORTITUDE-102 study enrolling, with the company expecting a peak product potential of > $1 billion. We look forward to the company achieving a CAGR of ~50% revenue growth from 2023 to 2028, driven by the sales of VYVGART and the three potential blockbuster products.

Expenses continued to be optimized, and the company's overall breakeven target by the end of 2025 was reaffirmed. In 2024Q2, the company's gross profit margin was 64.9% (-0.6pct), and we expect that the gross profit margin may improve with the release of VYVGART production capacity. In 2024Q2, R&D expenses accounted for $61.63 million (-19.6%), R&D expenses accounted for 61.6% (-49.8pct) of product revenue, and SG&A expenses were $79.71 million (+17.4%), and SG&A expenses accounted for 79.6% (-19.0pct) of product revenue, which was related to the increase in sales personnel and expenses of VYVGART. In 2024Q2, the company had a net loss of $80.28 million, compared with $120 million in the same period last year. Under the conditions of rapid revenue growth and expense optimization, the company reaffirmed its overall breakeven target by the end of 2025.

Further expand and advance the research and development of the global equity pipeline. In July 2024, the company as obtained global rights of a ROR1 ADC, expanding the pipeline. According to the conference call, the company still has a number of undisclosed pipelines in the preclinical stage, and aims to submit at least one global new drug clinical research application per year. In the global equity pipeline: 1) IL-17A has been studied in a global Phase II study for moderate to mild plaque psoriasis; 2) DLL3 ADC are expected to publish dose escalation data for 2L+ SCLC in late 2024-early 2025; 3) CCR8 Phase I PK/PD analysis is expected to be published at ESMO 2024.

Earnings Forecast and Valuation. Based on the sales performance of VYVGART and Optune, we adjust the revenue forecast for 2024-25 to $387/518 million, +45/34% yoy (prior: US$381/518 million), and we adjust the net profit forecast for 2024-25E to -$289/-159 million (prior: -US$288/ 159 million). We value the company according to the DCF model, using FY2025-31 cash flow to calculate, WACC of 9.9%, perpetual growth rate of 2.0%, assuming USD/HKD exchange rate of 1:7.83, corresponding to a target price of 65.76 HKD/share (previous value: 67.51 HKD/share), maintaining 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:

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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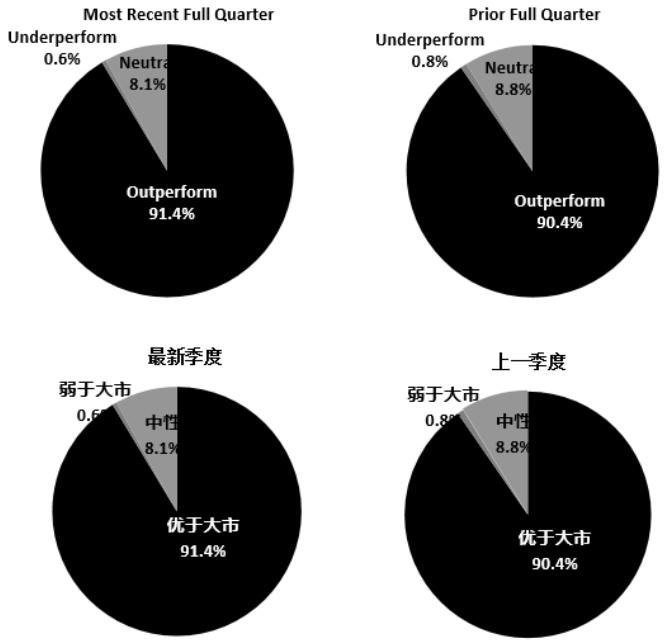

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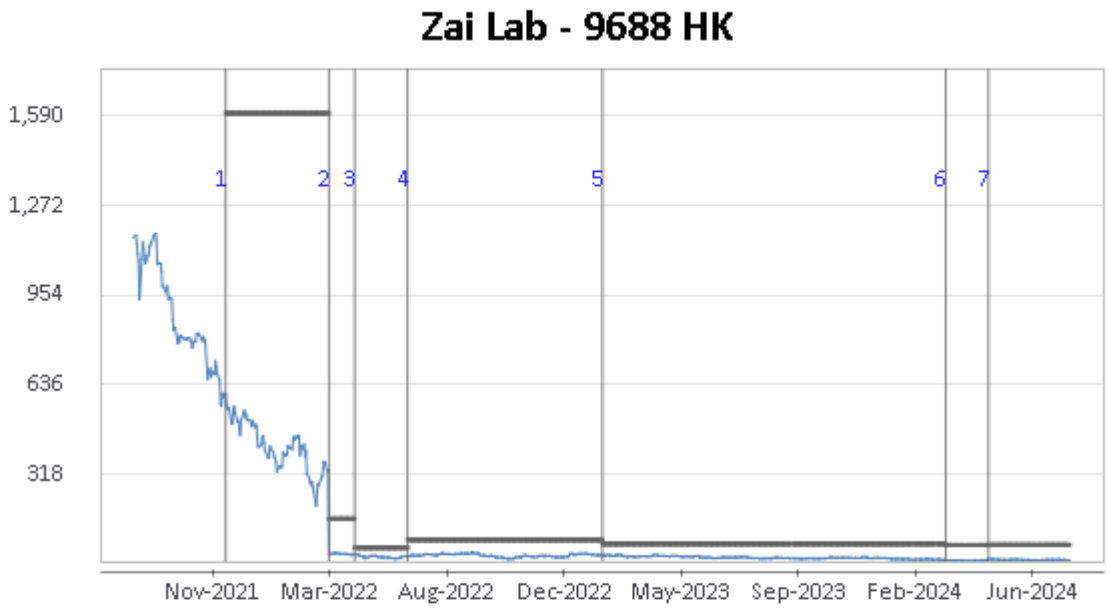

1. 29 Nov 2021 OUTPERFORM at 604.50 target 1600.00.
2. 29 Apr 2022 OUTPERFORM at 35.05 target 57.48.
3. 30 Jun 2022 OUTPERFORM at 26.60 target 85.23.
4. 13 Feb 2023 OUTPERFORM at 30.05 target 70.73.
5. 21 Mar 2024 OUTPERFORM at 13.84 target 66.82.
6. 10 May 2024 OUTPERFORM at 15.90 target 67.51.

10-for-1 split implemented on 30 Mar 2022