

再鼎医药 Zai Lab (9688 HK)

艾加莫德全年收入超预期, 2025年四季度有望实现扭亏 Efgartigimod Sales Beat; Management Guided Breakeven in 4Q25



观点聚焦 Investment Focus

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维持犹丁	大 P IVI	aintain Ol	JIPEKFOF	KIVI
评级			优于大市 Ol	JTPERFORM
现价				HK\$27.90
目标价				HK\$56.73
HTI ESG	Abo Annon di F			2.9-1.5-3.5
E-S-G: 0-5, (Please refer to	tne Appenaix Jo	or ESG comments)		
市值			HK\$30.59bn /	/ US\$3.94bn
日交易额 (3 个月均值)		ι	JS\$11.42mn
发行股票数目				1,096mn
自由流通股 (%)				86%
1年股价最高最低值			HK\$28.8	0-HK\$10.62
注: 现价 HK\$27.90 为	2025年03	月 10 日收盘价		
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Volume	1			
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Mar-24	Jul-24	l No	v-24	
资料来源: Factset				
绝对值		1mth 28.9%	3mth 28.0%	12mth 86.2%
绝对值(美元)		29.2%	28.1%	87.4%
相对 MSCI China		15.2%	8.2%	40.1%
ANA MISCI CIIIII		13.270	0.270	40.170
US\$ mn	Dec-23A	Dec-24A	Dec-25E	Dec-26E
Revenue	267	399	561	775
Revenue (+/-)	24%	50%	41%	38%
Net profit	-335	-257	-140	10
Net profit (+/-)	n.m.	n.m.	n.m.	n.m.
Diluted EPS (US\$)	-0.35	-0.26	-0.14	0.01
GPM	64.1%	62.9%	62.9%	64.9%
ROE	-42.0%	-30.6%	-19.4%	1.4%
P/E	n.m.	n.m.	n.m.	350.5

(Please see APPENDIX 1 for English summary)

事件

再鼎医药公布 2024 业绩:产品净收入 4.0 亿美元(同比+49%),其中核心产品艾加莫德(FcRn)收入 9360 万美元(23 年同期为 1000 万美元),毛利率 63.1%(-0.9pct)。R&D 费用 2.3 亿美元(-11.8%),R&D 费用率 58.8%(-40.9pct);SG&A 费用 3.0 亿美元(+6.1%),SG&A 费用率 74.9%(-30.7pct)。2024 年全年净亏损 2.6 亿美元(去年同期为 3.3 亿美元)。截至 2024 年底,公司在手现金、现金等价物、受限制现金 4.5 亿美元。管理层指引 2025年收入 5.6 亿美元至 5.9 亿美元,且到 4Q25 度实现 non-GAAP 经营利润盈利。

点评

艾加莫德全年收入超预期, 2025 年有望持续放量。

艾加莫德全年收入 9360 万美元,超过此前管理层指引的 8000 万美元,主要得益于其治疗重症肌无力(gMG)适应症 2024 年 1 月起纳入国家医保目录。管理层表示,2024 年每个月大约都有 1000 名新忠使用艾加莫德,4Q24 有 40%的三季度新患继续使用第二个疗程(第二季度/第三季度分别为 10%/30%)。2024 年 11 月,艾加莫德获批用于治疗慢性炎性脱髓鞘性多发性神经根神经病(CIDP)成人患者。我们预计艾加莫德凭借其两年独占期的先发优势,2025 年有望持续放量,收入规模有望超过 1.5 亿美元,是实现管理层 2025 年 5.6-5.9 亿美元收入指引的重要增长引擎。

多个潜在重磅产品接近商业化

1.2025年1月,NMPA已受理 KarXT 用于治疗成人精神分裂症的新药上市申请,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,2H25 有望读出三期临床数据。管理层指引 KarXT 峰值销售 10 亿美元(不包括阿尔兹海默)。2. 靶向 FGFR2b 的贝玛妥珠单抗(Bemarituzumab)预计将于 1H25 公布用于胃癌一线治疗的 3 期研究数据,并有望向 NMPA 提交上市申请。3.2025 年有望向 NMPA 提交肿瘤电场治疗(TTFields)用于 2L+ NSCLC 和 1L 胰腺癌的上市申请。我们认为,在以上三个重点产品以及艾加莫德的拉动下,公司 2024-2028 年有望实现 CAGR~40%的收入增长。

ZL-1310 是潜在 FIC 和 BIC,数据读出后有望加速海外授权

2025年1月,FDA 授予 ZL-1310 (DLL3 ADC) 孤儿药资格认定,用于治疗 SCLC。再鼎医药计划将在1H25 的重要医学会议上公布 ZL-1310 的 2L+广泛期 SCLC 的 ORR 和安全性数据,并在年内启动注册性临床研究,且正在和 FDA 沟通加速审批,最快将于2027年在美国上市。

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此外公司还会在其他神经内分泌肿瘤上启动一项全球 1 期临床。我们认为如果 ZL-1310 即将公布的临床数据能够延续此前披露的小范围人群数据(ORR 74%, n=19), ZL-1310 有望成为潜在 First-in-class 和 best-in-class 产品,并大大提高其海外授权可能性。

估值

考虑到艾加莫德超预期的商业化表现,我们调整 2025-26 年收入 预测为 5.6/7.8 亿美元(前值为 5.2/7.6 亿美元),同比 +41%/38%;我们预计得益于商业化超预期,公司有望在 2026 年实现净利润扭亏,调整 2025-26 年净利润预测为-1.4 亿/1010 万美元(前值为-1.6 亿/-915 万美元)。我们上调远期研发费用以反映 ZL-1310 等临床早期产品进入注册性临床后研发投入加大。我们根据 DCF 模型对公司进行估值,采用 2026-31 年现金流进行测算,WACC 为 9.9%(不变),永续增长率 2.0%(不变),对应目标价为56.73 港元(-14%),维持"优于大市"评级。

风险

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

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USD mn	FY23	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
	2023	2024	2025	2026	2027	2028	2029	2030	2031
Forecast Year				1.0	2.0	3.0	4.0	5.0	6.0
Time Factor				1.0	2.0	3.0	4.0	5.0	6.0
(fraction of year to next FY end))					42%			
Sales	266.7	399.0	561.2	775.1	1,115.4	1,621.9	2,159.1	2,698.1	3,285.7
Growth	24.0%	49.6%	40.6%	38.1%	43.9%	45.4%	33.1%	25.0%	21.8%
Gross Profit	170.9	251.1	353.2	503.4	729.9	1,069.5	1,434.5	1,800.8	2,202.7
GP Margin	64.1%	62.9%	62.9%	64.9%	65.4%	65.9%	66.4%	66.7%	67.0%
SG&A	-281.6	-298.7	-310.7	-323.1	-339.3	-460.9	-570.4	-658.8	-736.6
SG&A Margin	105.6%	74.9%	55.4%	41.7%	30.4%	28.4%	26.4%	24.4%	22.4%
Depreciation & Amortisation	9.0	9.0	8.1	9.8	11.7	14.0	17.4	21.9	27.3
EBIT	-366.6	-282.1	-165.1	-13.5	187.2	384.8	618.0	871.1	1168.3
Add: Amortisation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITA	-366.6	-282.1	-165.1	-13.5	187.2	384.8	618.0	871.1	1168.3
Margin	-137.4%	-70.7%	-29.4%	-1.7%	16.8%	23.7%	28.6%	32.3%	35.6%
Growth									
Add: Depreciation	9.0	9.0	8.1	9.8	11.7	14.0	17.4	21.9	27.3
EBITDA	-357.5	-273.1	-157.0	-3.7	198.9	398.7	635.3	893.0	1,195.6
Margin	-134.1%	-68.5%	-28.0%	-0.5%	17.8%	24.6%	29.4%	33.1%	36.4%
Less: Tax	0.0	0.0	0.0	-1.4	-25.5	-49.2	-77.2	-107.5	-139.7
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	-3.9	-11.0	-17.7	-22.2	-32.0	-31.9	-27.3	-27.1
Less: Capex	-7.2	-10.8	-16.8	-23.3	-22.3	-32.4	-43.2	-54.0	-65.7
Capex:Depreciation	0.8x	1.2x	2.1x	2.4x	1.9x	2.3x	2.5x	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	-516.0	-421.8	-318.8	-180.1	-5.0	151.1	349.1	570.2	829.1
FCF Growth	-16.1%	-18.3%	-24.4%	-43.5%	-97.2%	-3092.5%	131.1%	63.3%	45.4%
PV of FCF	-516.0	-421.8	-318.8	-163.8		113.7	239.1	355.2	469.8
WACC	(()	Chor Assum	o(ijores		DCF Valuation				
Risk Free Rate	1.5%				Sum of PV of FC	F			1,010
Market Risk Premium	10.0%				PV of Terminal \	/alue			6,043
Equity Beta	1.05				Enterprise Value	:			7,053
Cost of Equity	12.0%				Add: Net Cash				144
Cost of Debt (Pre-tax)	6.0%				Equity Value			_	7,196
Cost of Debt (After tax)	5.1%				No. of Ord share	es (m), fullv dil	uted		989
Target Debt weight	30.0%					(,,)			
Target Equity weight	70.0%				Value per Share	USD			7.27
Tax Rate	15.0%				FX: USD/HKD	,			7.80
WACC	9.9% T	erminal Grov	vth :	2.0%	Value per Share	e. HKD			\$56.73

资料来源: HTI

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Key ratios	2023A	2024E	2025E	2026E
EPS(USD)	-0.35	-0.26	-0.14	0.01
BVPS(USD)	0.82	0.85	0.73	0.74
Operating cash flow per share (USD	-0.21	-0.22	-0.13	0.01
DPS(USD)	0.00	0.00	0.00	0.00
P/E	n/a	n/a	n/a	350.50
P/B	4.34	4.21	4.90	4.84
P/S	5.95	3.98	2.83	2.05
EV/BITDA	(4)	(6)	(10)	(428)
Dividned yield	0%	0%	0%	0%
Gross margin	64%	63%	63%	65%
Net margin	-125%	-64%	-25%	1%
ROE	-42%	-31%	- 19 %	1%
ROA	-32%	-22%	-13%	1%
ROIC	-18%	-17%	-11%	1%
Revenue growth	24%	50%	41%	38%
EBIT growth	-9%	-23%	-41%	-92%
Net profit growth	-25%	-23%	-46%	- 10 7%
Asset/liability ratio	431%	344%	287%	269%
Liquidlityratio	463%	351%	283%	260%
Quickratio	441%	338%	266%	241%
Cashratio	389%	150%	83%	66%
AR days	89	82	82	82
Inventory days	171	98	98	98
Total asset turnover	26%	34%	51%	67%
Fixed asset turnover	276%	295%	390%	492%

Cash flow (USD mn)	2023A	2024E	2025E	2026E
Net profit	-335	-257	-140	10
Minorityinterests	0	0	0	0
Non-cash expenses	9	9	8	10
Non operating income	-40	-35	-35	-33
Change in working capital	17	4	-11	- 18
Operating cash flow	- 198	- 2 15	- 13 3	12
Assets	-7	-11	- 17	-23
Investment	-134	- 134	-134	-134
Others	130	-230	118	118
Investment cash flow	-11	- 375	-33	-40
Increase in debts	0	131	0	0
Proceeds from issue of shares	2	217	0	0
Others	-9	1	0	0
Financing cash flow	- 6	350	0	0
Net cash inflow	-215	-240	- 16 6	-28

IS (USD mn)	2023A	2024E	2025E	2026E
Revenue	267	399	561	775
COGS	96	148	208	272
GPM (%)	64%	63%	63%	65%
Business tax and surcharges	0	0	0	1
Taxrate(%)	0.0%	0.0%	0.0%	12.0%
Operating expense	282	299	311	323
Operating expense ratio (%)	105.6%	74.9%	55.4%	417%
Administrative expense				
Administrative expense ratio (%)				
⊞IT	-367	-282	-165	-14
Financing expense	0	0	0	0
Financing expense ratio (%)	0.0%	0.0%	0.0%	0.0%
Assets impairment loss				
Investment profit	40	35	35	35
Operating profit	-367	-282	- 16 5	- 14
Exceptional income-net	0	0	0	0
Pre-tax profit	-335	-257	- 14 0	11
⊞ITDA	-358	-273	- 157	-4
Taxation	0	0	0	1
Taxrate(%)	0	0	0	0
Minorityinterests	0	0	0	0
Net income to ord equity	-335	-257	- 14 0	10

Financial statement (USD mn)	2023A	2024E	2025E	2026E
Cash	790	450	283	256
Account receivable	65	89	126	174
Inventory	45	40	56	73
Other current assets	39	472	499	505
Total current assets	940	1050	964	1008
Long-term equity investment				
Tangible assets	78	73	81	95
Construction in progress				
Int angible assets	13	56	56	56
Total non-current assets	97	135	144	157
Total assets	1036	1186	1108	1166
Short-term debts	7	140	140	140
Account payable	113	101	142	190
Prepayments	0	0	0	0
Other current liabilities	83	59	59	59
Total current liabilities	203	299	341	388
Long-term debts	0	0	0	0
Other long-term liabilities	37	45	45	45
Total non-current liabilities	37	45	45	45
Total liabilities	240	345	386	434
Common stocks	796	841	722	732
Retain earnings reserves	-2 158	-2403	-2543	-2533
Minorityinterests	0	0	0	0
Total liabilities and equities	1036	1186	1108	1166

资料来源: HTI

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APPENDIX 1

Summary

What's new: Zai Lab announced FY24 results

Zai Lab achieved product net revenue of USD400mn in FY24, +49% y-y. Sales of its core product Efgartigimod came in at USD93.6mn (compared to USD10mn in FY23). GPM was 63.1% (-0.9ppts y-y). R&D expenses were USD235mn (-11.8% y-y), with an R&D expense ratio of 58.8% (-40ppts). SG&A expenses were USD299mn (+6.1% y-y), with an SG&A expense ratio of 74.9% (-30.7ppts). Net loss for FY24 was USD257mn (compared to USD335mn in FY23). As of the end of FY24, the company had USD450mn in cash, cash equivalents, and restricted cash. Management guides sales of USD560-590mn in FY25 and to achieve non-GAAP operating profitability by 4Q25.

Sales of Efgartigimod beat; we expect its sales to continue growing in FY25

Efgartigimod generated sales of USD93.6mn in FY24, beating the management's previous guidance of USD80mn. This was largely due to its inclusion in the National Reimbursement Drug List (NRDL) for the treatment of generalized myasthenia gravis (gMG) since January 2024. Management noted that c.1,000 new patients used Efgartigimod each month in 2024. In 4Q24, c.40% of new patients from 3Q24 continued into their second treatment course (compared to 10% and 30% in 2Q24 and 3Q24, respectively). In November 2024, Efgartigimod was approved for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. We anticipate that Efgartigimod, with its two-year exclusivity advantage, will continue to grow in FY25, potentially exceeding USD150mn in revenue. This makes it a crucial growth driver for achieving the management's 2025 revenue guidance of USD560-590mn.

Several potential blockbuster products are nearing commercialization:

1. KarXT: As of January 2025, the NMPA has accepted the new drug application (NDA) for KarXT to treat adult schizophrenia. Additionally, KarXT has been added to a global Phase III clinical trial for treating psychiatric symptoms caused by Alzheimer's disease, with Phase III data expected in 2H25. Management guidance suggests peak sales of USD1bn for KarXT (excluding Alzheimer's indications). 2. Bemarituzumab (FGFR2b): Bema is expected to release Phase III study data for first-line gastric cancer treatment in 1H25 and may submit the NDA to the NMPA. 3. Tumor Treating Fields (TTFields): In 2025, an application is expected to be submitted to the NMPA for TTFields to treat second-line non-small cell lung cancer (NSCLC) and first-line pancreatic cancer. We believe that these key products, along with Efgartigimod, will drive the company's revenue growth at a compound annual growth rate (CAGR) of c.40% from FY24 to FY28.

ZL-1310, a potential FIC and BIC product; we expect to accelerate overseas out-licensing after and its data readout

In January 2025, the FDA granted ZL-1310 (DLL3 ADC) orphan drug designation for the treatment of small cell lung cancer (SCLC). Zai Lab plans to present ZL-1310's objective response rate (ORR) and safety data for second-line or later extensive-stage SCLC at a major medical conference in 1H25. The company will also initiate registrational clinical studies within the year and is in discussions with the FDA for accelerated approval, aiming for the earliest possible U.S. launch in 2027. Additionally, Zai Lab will start a global Phase I clinical trial for other neuroendocrine tumors in 2025. We believe that if ZL-1310's upcoming clinical data can sustain the previously disclosed results (ORR of 74%, n=19), it is likely to become a potential FIC and BIC product, significantly increasing its chances of overseas out-licensing.

Earnings Forecast and Valuation.

Given Efgartigimod's better-than-expected commercial performance, we have adjusted our revenue forecasts for FY25 and FY26 to USD561mn and USD775mn, respectively (previously USD518mn and USD759mn), +41% and +38% y-y growth. We believe that, driven by Efgartigimod's strong commercial performance, the company will achieve a breakeven in FY26. Consequently, we fine-tune the net profit forecast for FY25 and FY26 to USD-140mn and USD10mn, respectively (previously USD-159mn and USD-9mn). We have also increased our long-term R&D expense estimates to reflect the increased investment in clinical trials as early-stage products like ZL-1310 enter registrational studies. Using a discounted cash flow (DCF) model to value the company, based on cash flows from FY26 to FY31, with a weighted average cost of capital (WACC) of 9.9% (unchanged) and a perpetual growth rate of 2.0% (unchanged), we derive a TP of HKD56.73. We maintain our "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.

海通國際 HAITONG

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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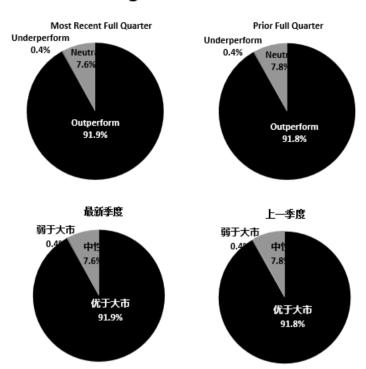
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		(hold)	
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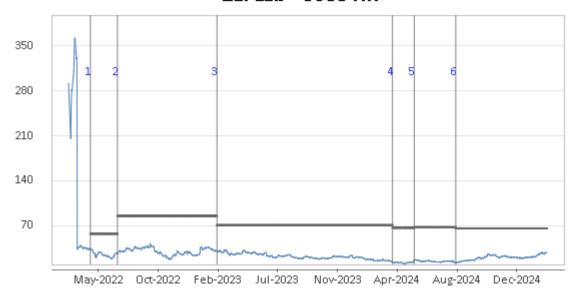
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Zai Lab - 9688 HK



- 1. 29 Apr 2022 OUTPERFORM at 35.05 target 57.48.
- 2. 30 Jun 2022 OUTPERFORM at 26.60 target 85.23.
- 3. 13 Feb 2023 OUTPERFORM at 30.05 target 70.73.
- 4. 21 Mar 2024 OUTPERFORM at 13.84 target 66.82.
- 5. 10 May 2024 OUTPERFORM at 15.90 target 67.51.
- 6. 13 Aug 2024 OUTPERFORM at 12.50 target 65.76.

Source: Company data Bloomberg, HTI estimates