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## 业绩拐点已至，公司大步迈入创新药放量新周期

### 投资要点：

- 我们认为 2024 年是公司的业绩拐点，公司已进入新药放量的成长新周期。2022-2023 年，我们判断由于核心产品埃克替尼医保降价以及 NSCLC 市场竞争加剧，公司收入增速有所下滑，同比增速跌至 6% 及 3%。2023 年以来，公司新上市创新药的核心适应症陆续进入医保并在 2024 年开始快速放量，带动公司业绩重回高增长。
- 我们认为随着公司持续进行研发战略优化，其内部研发费用率或阶段性降低，带动利润更快增长；同时，鉴于公司长期以来优秀的外部合作能力，我们持续看好公司从外部引入潜力管线的能力。公司长期秉持“自主研发、战略合作、市场销售、创新生态圈”四驾马车协同发展的战略。2024 年以来，我们认为公司在自研方面将进一步优化管线质量，更聚焦于重点管线开发，公司研发费用率阶段性有所降低；在战略合作方面，公司通过贝达梦工场、产业基金等方式持续打造创新生态圈，不断提升战略合作和自研的互补协同，丰富公司管线。
- 公司在研管线质地优秀，我们认为其中部分或存在对外授权机会，或良好的数据读出预期。根据贝达药业 2024 年半年报披露，公司目前有 10 余款在研新药处于临床阶段，我们一方面看好部分临床后期管线如 EYP1901 在全球成为下一款眼科重磅药物的潜力，以及恩沙替尼在欧美获批上市销售的潜力 (FDA PDUFA20241228)；另一方面建议持续关注公司早期管线中全球进度领先药物的进展，包括 CFT8919 (BiDAC 降解剂)、BPI-460372 (TEAD 抑制剂)、BPI-452080 (HIF-2 $\alpha$  抑制剂)、BPI-371153 (PDL1 口服抑制剂)、BPB-101 (GARP\*PDL1 双抗) 等。
- 盈利预测。我们预测公司 2024-2026 年营收收入分别为 30.00、40.60、52.62 亿元，同比增长 22.1%、35.3%、29.6%；净利润分别为 5.07、8.94、13.12 亿元；EPS 分别为 1.21、2.14、3.14 元。利用可比公司估值法，我们给予其 2024 年 57 倍 PE，对应目标价 69.08 元，给予“优于大市”评级。
- 风险提示：研发创新不及预期风险；行业政策风险；市场竞争加剧风险；

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### 主要财务数据及预测

	2022	2023	2024E	2025E	2026E
营业收入 (百万元)	2377	2456	3000	4060	5262
(+/-)YoY(%)	5.8%	3.3%	22.1%	35.3%	29.6%
净利润 (百万元)	145	348	507	894	1312
(+/-)YoY(%)	-62.0%	139.3%	45.7%	76.3%	46.8%
全面摊薄 EPS(元)	0.35	0.83	1.21	2.14	3.14
毛利率(%)	88.7%	83.5%	86.5%	87.8%	88.0%
净资产收益率(%)	3.0%	6.6%	9.0%	14.0%	17.7%

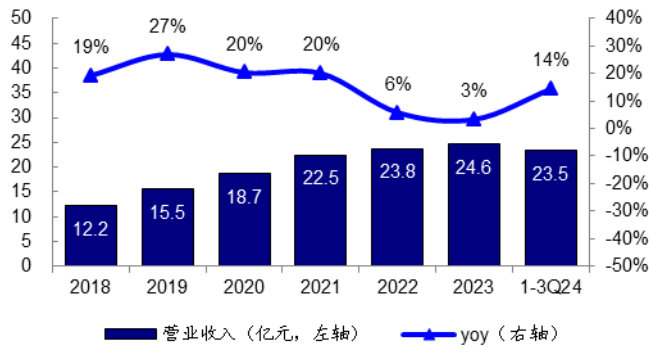
资料来源：公司年报 (2022-2023)，HTI

备注：净利润为归属母公司所有者的净利润

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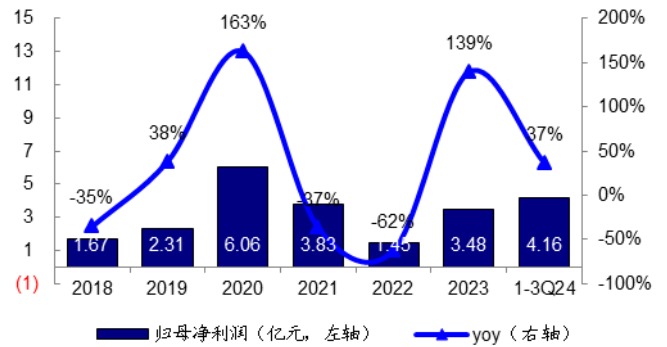
我们认为 2024 年是公司的业绩拐点，公司已进入新药放量的成长新周期。2022-2023 年，我们判断由于核心产品埃克替尼医保降价以及 NSCLC 市场竞争加剧，公司收入增速有所下滑，同比增速跌至 6% 及 3%。2023 年以来，公司新上市创新药的核心适应症陆续进入医保并在 2024 年开始快速放量（表 1），带动公司业绩重回高增长。

图1 2018-3Q2024 贝达药业营业收入情况



资料来源：WIND, HTI

图2 2018-3Q2024 贝达药业归母净利润情况



资料来源：WIND, HTI

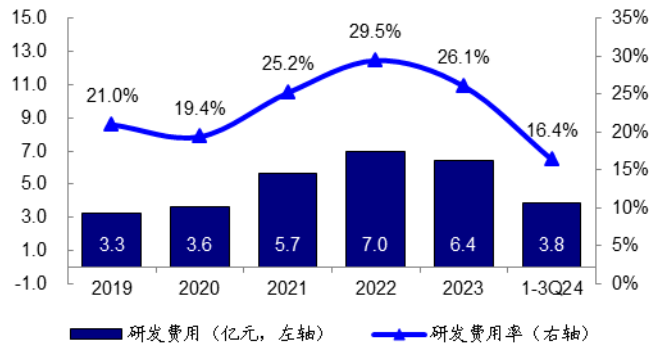
表 1 贝达药业处于临床后期或已上市阶段药物汇总

药物名称	靶点	适应症	临床阶段	医保情况
埃克替尼	EGFR	既往化疗治疗失败后的二线 NSCLC	2011/6 上市	2017/2 纳入医保
		EGFR NSCLC 一线治疗	2014/11 上市	2017/2 纳入医保
		II-III 期 EGFR NSCLC 术后辅助	2021/6 上市	2021/12 纳入医保
恩沙替尼	ALK	克唑替尼治疗后进展的 ALK NSCLC 二线治疗	2020/11 上市	2021/12 纳入医保
		ALK NSCLC 一线治疗	2022/3 上市	2023/1 纳入医保
		ALK NSCLC 一线治疗（全球）	NDA, PDUFA2024/12/28	-
贝伐珠单抗	VEGF	晚期 CRC、NSCLC	2021/11 上市	-
		晚期宫颈癌、胶质母细胞瘤等	2022/3 上市	-
贝福替尼	EGFR	EGFR TKI 经治且伴随 T790M 突变的二线治疗	2023/5 上市	2023/12 纳入医保
		EGFR 外显子 19 缺失或 L858R 突变的 NSCLC 一线治疗	2023/10 上市	2025/1 纳入医保
		IB-III 期 EGFR NSCLC 术后辅助治疗	III 期	-
伏罗尼布	VEGFR	联用依维莫司，用于既往酪氨酸酶抑制剂治疗失败的 RCC	2023/6 上市	2023/12 纳入医保
泰贝西利	CDK4/6	联合氟维司群治疗内分泌治疗后进展的 HR+/HER2-乳腺癌	NDA, 预计 2025 上市	-
HY1001	植物源重组人血白蛋白	低蛋白血症	NDA, 预计 2025 上市	-

资料来源：贝达药业半年报，xcovery 公司官网，国家医保局，insight 数据库，HTI 汇总；注：泰贝西利和 HY1001 上市时间为 HTI 预测

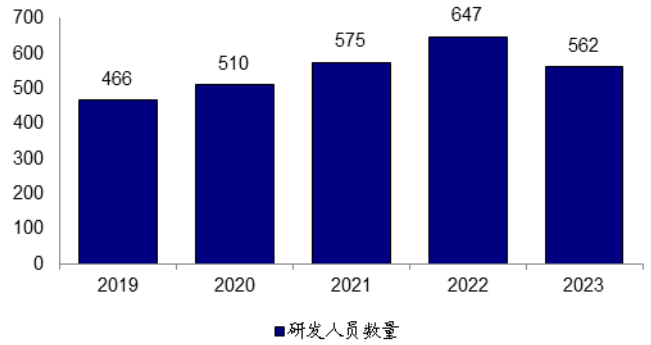
我们认为随着公司持续进行研发战略优化，其内部研发费用率或阶段性降低，带动利润更快增长。2024 年以来，我们认为公司在自研方面进一步优化管线质量，更聚焦于重点管线开发，公司研发费用率阶段性有所降低。

图3 2019-3Q2024 贝达药业研发费用情况



资料来源: WIND, HTI

图4 2019-2023 贝达药业研发人员数量情况 (人)



资料来源: WIND, HTI

同时, 鉴于公司长期以来优秀的外部合作能力, 我们持续看好公司从外部引入潜力管线的能力。公司长期秉持“自主研发、战略合作、市场销售、创新生态圈”四驾马车协同发展的战略。在战略合作方面, 公司通过贝达梦工场、产业基金等方式持续打造创新生态圈, 不断提升战略合作和自研的互补协同, 丰富公司管线。

表 2 贝达药业创新生态圈部分公司情况汇总

公司名称	与贝达合作情况	部分在研管线	备注
启元生物	贝达基金天使轮投资	QY101	PDE4 吸入剂、外用乳膏
		QY201	JAK1/TYK2 抑制剂
瑞普晨创	贝达药业战略合作	RGB-5088	胰岛细胞注射液
禾元生物	贝达药业 pre-IPO 领投; 签订 HY1001 区域经销协定	HY1001	植物源重组人血白蛋白
泽德曼生物	贝达基金 A 轮/A+轮投资	本维莫德乳膏	AhR 调节剂
圣域生物	贝达基金投资	SYN818	DNA 聚合酶 θ
时迈药业	贝达药业持股	DNV3	LAG3 单抗
		SMET12	CD3*EGFR 双抗
邦耀生物	贝达基金 B 轮/B+轮投资	BRL303	针对自免的异体通用型 CAR-T
维眸生物	贝达基金 C 轮/D 轮投资	VVN001 滴眼液	LFA-1 拮抗剂
三叶草生物	贝达产业基金 B 轮投资	SCB1019	RSV 疫苗
天广实	贝达药业持股; 买断贝安汀 (贝伐珠单抗) 销售权	MIL62	针对自免的 CD20 单抗
纽安津	贝达基金 A 轮投资	P01	个体化肿瘤新生抗原多肽疫苗
康万达	贝达基金战略投资	hv01	溶瘤痘苗病毒
瑞普基因	贝达药业签订市场推广协议	-	基因检测公司
多禧生物	贝达药业投资	DX126-262	HER2 ADC
		DAC-002	TROP2 ADC
华昊中天	贝达药业投资	优替德隆	微管抑制剂

资料来源: 贝达药业官网, 贝达基金公众号, HTI 汇总;

公司在研管线质地优秀, 我们认为其中部分或存在对外授权机会, 或良好的数据读出预期。根据贝达药业 2024 年半年报披露, 公司目前有 10 余款在研新药处于临床阶段。

临床后期管线中, 公司与 EYEPOINT 合作开发的 EYP1901 有成为全球成为下一款眼科重磅药物的潜力。EYP1901 针对 wAMD 适应症的全球 II 期临床 DAVIO 2 已于 2023/12 达到临床终点, 在六个月内仅一次给药的情况下 (阿柏西普三次给药), 疗效上达到统计学非劣, 并展现出良好的安全性和依从性, 全球 III 期临床已于 2024 年启动。此外, EYP1901 针对 DME 的全球 II 期临床 VERONA 已在 2024/10 披露中期数据, 相较于阿柏西普展现出更优的疗效以及良好的安全性和依从性, 完整数据预计将在 1Q2025 披露。贝达药业拥有 EYP1901 中国地区的权益, 并已启动 wAMD 的临床试验。

恩沙替尼有望成为公司首个在欧美获批上市销售的产品。恩沙替尼已经向 FDA 递交上市申请, PDUFA 为 2024/12/28。

建议持续关注早期管线中全球进度领先药物的进展。包括 CFT8919 (BiDAC 降解剂)、BPI-460372 (TEAD 抑制剂)、BPI-452080 (HIF-2α 抑制剂)、BPI-371153 (PDL1 口服抑制剂)、BPB-101 (GARP\*PDL1 双抗) 等。

表 3 贝达药业在研临床情况

药物名称	MOA	适应症	给药方式	临床阶段	进展	负责机构
EYP1901	伏罗尼布玻璃体内植入剂	wAMD	单药	中国 II 期	-	贝达药业/EYEPOINT
MCLA129	EGFR*CMET 双抗	一线/二线 NSCLC	联合贝福替尼	中国 I 期	2023/9 FPI	贝达药业/MERUS
MRX2843	MERTK*FLT3 抑制剂	晚期实体瘤	单药	全球 I 期	2018 FPI, 预计 2025 完成	XCOVERY
		r/r AML、ALL、MPAL	单药	全球 I 期	2022 FPI, 预计 2026 完成	XCOVERY
		晚期实体瘤	单药	中国 I 期	2020 启动	贝达药业
CFT8919	BiDAC 降解剂	后线 NSCLC	单药	中国 I 期	2024/11 FPI	贝达药业/C4 THERAPUTICS
Balstilimab+Zalifrelimab	PD1 单抗+CTLA4 单抗	宫颈癌	联用	中国 II 期	-	贝达药业
BPI-472372	CD73 抑制剂	晚期实体瘤	单药	中国 I 期	-	贝达药业
BPI-460372	TEAD 抑制剂	间皮瘤、血管肉瘤等实体瘤	单药	中国 I 期	已完成, 2024AACR 披露数据	贝达药业
BPI-452080	HIF-2 $\alpha$ 抑制剂	VHL 综合征相关肿瘤	单药	中国 I 期	2024IND 受理	贝达药业
BPI-442096	SHP2 抑制剂	后线胰腺癌、结直肠癌、NSCLC 等	单药	中国 I 期	2022/7 FPI, 预计 2025 完成	贝达药业
BPI-371153	PDL1 抑制剂	晚期实体瘤	单药	中国 I 期	2022/8 FPI, 预计 2025 完成	贝达药业
BPI-361175	四代 EGFR-TKI	C797S 突变 NSCLC	单药	全球 I/II 期	2023/7 FPI	XCOVERY
BPI-21668	PI3K $\alpha$ 选择性抑制剂	晚期实体瘤	单药	中国 I 期	2022/1 FPI, 预计 2025 完成	贝达药业
BPB-101	GARP*PDL1 双抗	晚期实体瘤	单药	中国 I/II 期	2023/5 FPI, 预计 2025 完成	贝达药业
BPI-221351	IDH1/IDH2 抑制剂	胆管癌等实体瘤	单药	中国 I 期	2024/3 批准临床	贝达药业
BPI-520105	pan-EGFR 抑制剂	晚期实体瘤	单药	中国 I 期	2024/4 批准临床	贝达药业

资料来源: 贝达药业 2024 半年报, insight 数据库, EYEPOINT、MERUS、XCOVERY 官网等, HTI 汇总;

表 4 贝达药业 2022-2026E 收入拆分

	2022	2023	2024E	2025E	2026E
埃克替尼	17.00	15.80	14.00	12.00	10.00
YOY	-18.1%	-7.1%	-11.4%	-14.3%	-16.7%
恩沙替尼	4.40	6.10	9.00	12.00	16.00
YOY		38.6%	47.5%	33.3%	33.3%
贝福替尼		0.60	3.00	9.00	13.79
YOY			400.0%	200.0%	53.3%
贝伐珠单抗	1.00	2.00	3.00	4.00	5.00
YOY		100.0%	50.0%	33.3%	25.0%
泰贝西利				1.05	2.50
YOY					138.0%
伏罗尼布		0.06	1.00	2.05	2.28
YOY				104.6%	11.3%
MCLA-129					0.05
YOY					
人血白蛋白-分成后				0.20	1.20
其他收入	1.37	0.00	0.00	0.00	0.00
总收入 (亿元)	23.77	24.56	30.00	40.60	52.62
YOY	5.8%	3.3%	22.1%	35.3%	29.6%

资料来源: WIND, HTI 预测;

表 5 可比公司估值表

股票代码	公司名称	股价 (元)	EPS (元)				PE (倍)			
		2024/12/12	2023	2024E	2025E	2026E	2023	2024E	2025E	2026E
600276.SH	恒瑞医药	48.04	0.67	0.94	1.05	1.26	71.23	51.26	45.59	38.09
002294.SZ	信立泰	34.18	0.52	0.56	0.64	0.77	65.69	60.69	53.20	44.25
688578.SH	艾力斯	62.24	1.43	2.82	3.43	4.02	43.48	22.04	18.13	15.47
688336.SH	三生国健	22.60	0.48	0.96	0.49	0.58	47.31	23.46	46.31	38.95
	均值						56.93	39.37	40.81	34.19

资料来源: Wind, HTI; 注: 收盘价为 2024 年 12 月 12 日价格, 可比公司 EPS 为 Wind 一致预期

## 财务报表分析和预测

主要财务指标	2023	2024E	2025E	2026E	利润表 (百万元)	2023	2024E	2025E	2026E
<b>每股指标 (元)</b>					<b>营业总收入</b>	2456	3000	4060	5262
每股收益	0.83	1.21	2.14	3.14	营业成本	404	405	495	629
每股净资产	12.55	13.52	15.23	17.74	毛利率%	83.5%	86.5%	87.8%	88.0%
每股经营现金流	2.18	0.73	3.12	3.06	营业税金及附加	14	20	27	33
每股股利	0.17	0.24	0.43	0.63	营业税金率%	0.6%	0.7%	0.7%	0.6%
<b>价值评估 (倍)</b>					营业费用	854	1140	1563	1973
P/E	65.75	45.12	25.59	17.44	营业费用率%	34.8%	38.0%	38.5%	37.5%
P/B	4.36	4.05	3.59	3.08	管理费用	262	378	512	663
P/S	9.32	7.63	5.64	4.35	管理费用率%	10.7%	12.6%	12.6%	12.6%
EV/EBITDA	37.09	32.62	20.48	14.55	EBIT	323	584	1014	1486
股息率%	0.3%	0.4%	0.8%	1.1%	财务费用	40	0	0	0
<b>盈利能力指标 (%)</b>					财务费用率%	1.6%	0.0%	0.0%	0.0%
毛利率	83.5%	86.5%	87.8%	88.0%	资产减值损失	0	0	0	0
净利润率	14.2%	16.9%	22.0%	24.9%	投资收益	-13	-9	-12	-16
净资产收益率	6.6%	9.0%	14.0%	17.7%	<b>营业利润</b>	<b>270</b>	<b>575</b>	<b>1002</b>	<b>1470</b>
资产回报率	3.8%	5.6%	8.7%	11.8%	营业外收支	52	-6	0	0
投资回报率	4.3%	6.1%	9.9%	13.2%	<b>利润总额</b>	<b>322</b>	<b>568</b>	<b>1002</b>	<b>1470</b>
<b>盈利增长 (%)</b>					EBITDA	627	769	1204	1682
营业收入增长率	3.3%	22.1%	35.3%	29.6%	所得税	-12	85	150	221
EBIT 增长率	57.0%	80.5%	73.8%	46.6%	有效所得税率%	-3.6%	15.0%	15.0%	15.0%
净利润增长率	139.3%	45.7%	76.3%	46.8%	少数股东损益	-14	-24	-43	-62
<b>偿债能力指标</b>					<b>归属母公司所有者净利润</b>	<b>348</b>	<b>507</b>	<b>894</b>	<b>1312</b>
资产负债率	41.5%	36.3%	38.0%	33.3%					
流动比率	0.85	0.67	0.87	1.08	<b>资产负债表 (百万元)</b>	<b>2023</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>
速动比率	0.58	0.42	0.53	0.74	货币资金	752	157	491	611
现金比率	0.42	0.12	0.25	0.36	应收账款及应收票据	286	239	472	449
<b>经营效率指标</b>					存货	328	165	438	328
应收账款周转天数	52.74	30.00	30.00	30.00	其它流动资产	160	296	275	432
存货周转天数	311.36	219.00	219.00	219.00	流动资产合计	1526	857	1675	1820
总资产周转率	0.29	0.33	0.42	0.49	长期股权投资	375	375	375	375
固定资产周转率	4.39	5.63	7.43	9.48	固定资产	524	541	552	558
					在建工程	2037	2437	2837	3237
					无形资产	1944	2044	2144	2344
					非流动资产合计	7621	8138	8651	9258
<b>现金流量表 (百万元)</b>	<b>2023</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>	<b>资产总计</b>	<b>9147</b>	<b>8995</b>	<b>10325</b>	<b>11078</b>
净利润	348	507	894	1312	短期借款	300	220	140	60
少数股东损益	-14	-24	-43	-62	应付票据及应付账款	800	407	1070	807
非现金支出	312	185	190	195	预收账款	1	1	2	2
非经营收益	51	15	12	16	其它流动负债	702	641	716	824
营运资金变动	217	-379	253	-179	流动负债合计	1803	1270	1927	1693
<b>经营活动现金流</b>	<b>914</b>	<b>305</b>	<b>1307</b>	<b>1282</b>	长期借款	1816	1816	1816	1816
资产	-1074	-691	-685	-785	其它长期负债	176	176	176	176
投资	-432	-18	-18	-18	非流动负债合计	1992	1992	1992	1992
其他	0	-9	-12	-16	<b>负债总计</b>	<b>3795</b>	<b>3262</b>	<b>3920</b>	<b>3685</b>
<b>投资活动现金流</b>	<b>-1505</b>	<b>-718</b>	<b>-715</b>	<b>-818</b>	实收资本	418	418	418	418
债权募资	1379	-80	-80	-80	归属于母公司所有者权益	5251	5657	6372	7422
股权募资	61	0	0	0	少数股东权益	100	76	34	-29
其他	-832	-101	-179	-262	<b>负债和所有者权益合计</b>	<b>9147</b>	<b>8995</b>	<b>10325</b>	<b>11078</b>
<b>融资活动现金流</b>	<b>608</b>	<b>-182</b>	<b>-259</b>	<b>-343</b>					
<b>现金净流量</b>	<b>21</b>	<b>-595</b>	<b>333</b>	<b>121</b>					

备注: (1) 表中计算估值指标的收盘价日期为 12 月 12 日; (2) 以上各表均为简表

资料来源: 公司年报 (2023), HTI

## APPENDIX 1

## Summary

## Investment Highlights:

We believe 2024 marks a performance turning point for the company, entering a new growth cycle with new drugs. In 2022-2023, revenue growth slowed to 6% and 3% YoY due to Icotinib's price cut and increased NSCLC competition. Since 2023, new innovative drugs have entered insurance, boosting high growth in 2024. With optimized R&D strategies, internal R&D expenses may temporarily decrease, accelerating profit growth. The company's strong external collaboration continues to enhance its pipeline. The strategy focuses on 'independent R&D, strategic cooperation, market sales, and innovation ecosystem'. Since 2024, the company has optimized pipeline quality, focusing on key developments, reducing R&D expenses. Strategic cooperation through Betta Dream Factory and industry funds enriches the pipeline. The company has over 10 clinical-stage new drugs, with potential for external licensing or positive data outcomes. We see potential in late-stage pipelines like EYP1901 as a global ophthalmic drug and Ensartinib's approval in the US and Europe (FDA PDUFA20241228). Early pipeline progress includes CFT8919, BPI-460372, BPI-452080, BPI-371153, BPB-101. Profit Forecast: We project 2024-2026 revenue at 3.00, 4.06, 5.26 billion RMB, growing 22.1%, 35.3%, 29.6% YoY; net profit at 0.51, 0.89, 1.31 billion RMB; EPS at 1.21, 2.14, 3.14 RMB. Using comparable company valuation, we give a 57x PE for 2024, target price 69.08 RMB, and an 'Outperform' rating.

Risk Warning: Risks include weaker than expected R&D innovation, industry policy risks, and intensified market competition.

## 附录 APPENDIX

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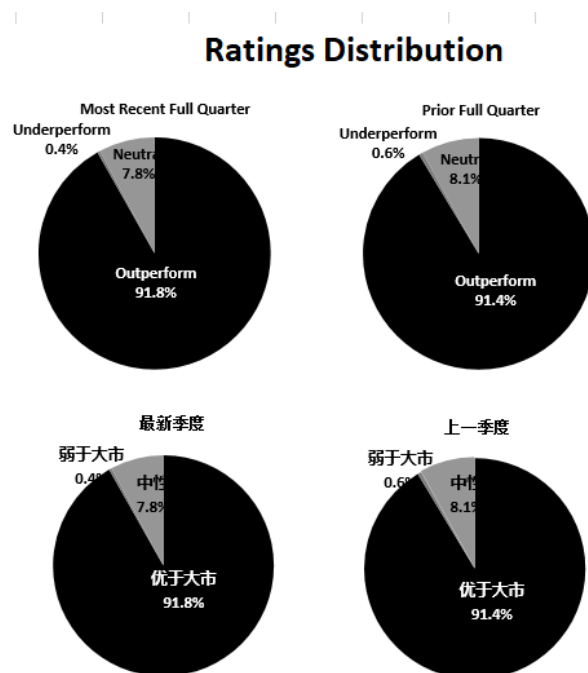
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#### 截至 2024 年 9 月 30 日海通国际股票研究评级分布

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\*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。

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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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IB clients*	3.5%	4.4%	0.0%

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