



2024/7/4

產業類別	生技
投資建議	中立 
收盤價	目標價
NT\$ 84.10	NT\$

本次報告：法說會

## 交易資料

潛在報酬率 (%)	--
52 週還原收盤價區間 (NT\$)	76.40-107.00
市值 (NT\$百萬元)	11430
市值 (US\$百萬美元)	350
流通在外股數 (百萬股)	136.00
董監持股 (%)	17.58
外資持股 (%)	26.03
投信持股 (%)	0.00
融資使用率 (%)	--

## 財務資料

	2023
股東權益 (NT\$百萬元)	1,245
ROA (%)	-65.48
ROE (%)	-96.17
淨負債比率 (%)	33.14

## 公司簡介

逸達為一採雙領域聚焦研發之生技公司：逸達運用穩定注射劑型技術(SIF, Stabilized Injectable Formulation)研發新劑型新藥，並採 505(b)2 途徑聚焦特殊用藥市場，目前前列腺癌藥 Camcevi 42mg 六個月長效注射劑型已取得美國、加拿大、歐盟及台灣藥品上市許可，歐洲市場預計今年年底上市，逸達以口服 MMP-21 抑制劑及口服 ALDH2 活化劑系列化合物進行多重適應症之藥品開發。

主要客戶：

主要競爭對手：

陳奕均 fion.chen@sinopac.com

## 逸達 (6576 TT)

繼續觀察

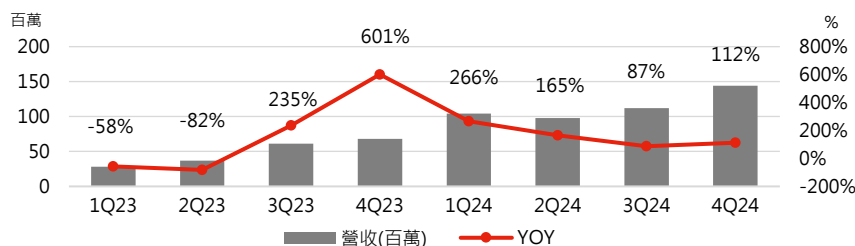
### 永豐觀點

目前營收仍尚未達營運轉盈規模。

### 投資評價與建議

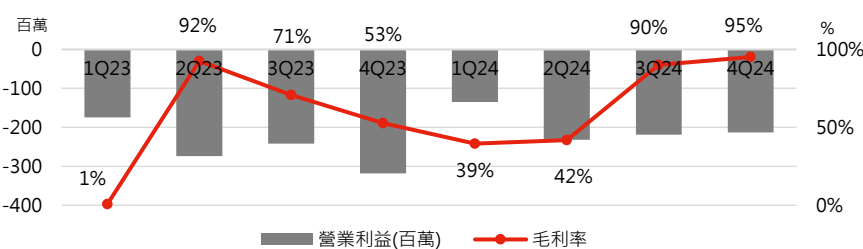
**投資建議中立：**雖前列腺癌藥物 Camcevi 六個月劑型為逸達成功進入美國市場之敲門磚，惟考量目前營收尚未達營運轉盈規模且新藥授權機會較大時間點多落於 2H25 年後，故建議中立。後續將持續關注 3 個月主流劑型美國市場藥證申請進度及開發中新藥授權之狀況再予以評估。

### 近八季營收及 YoY 趨勢圖



資料來源：CMoney；永豐投顧研究處整理，Jul 2024

### 近八季營業利益及毛利率趨勢圖



資料來源：CMoney；永豐投顧研究處整理，Jul. 2024

## 營運現況與分析



逸達為一採雙領域聚焦研發之生技公司：逸達運用穩定注射劑型技術(SIF, Stabilized Injectable Formulation)研發新劑型新藥，並採 505(b)2 途徑聚焦特殊用藥市場，目前前列腺癌藥 Camcevi 42mg 六個月長效注射劑型已取得美國、加拿大、歐盟及台灣藥品上市許可，歐洲市場預計今年年底上市，21mg 三個月長效注射劑型預計 2H24 向 US FDA 提出藥證申請，新藥部分，逸達以口服 MMP-21 抑制劑及口服 ALDH2 活化劑系列化合物進行多重適應症之藥品開發。

圖一：逸達 SIF 技術平台新劑型新藥研發進程

專案/產品	適應症	藥物探索	臨床前/一期臨床	二期臨床	法規審理
 <b>CAMCEVI<sup>®</sup> (FP-001)</b> Leuprolide	前列腺癌	CAMCEVI 42 mg (FP-001 50 mg, 6個月劑型)	美國/加拿大/歐盟/台灣藥證核准、以色列/英國藥證審查中 *2022/4月美國上市		
		CAMCEVI 21 mg (FP-001 25 mg, 3個月劑型)	法規審理申請預備 (預計2024年下半年申請美國藥證)		
	兒童中樞性早熟	FP-001 42 mg (6個月劑型)	二期臨床試驗進行中		
	停經前乳癌 (HR+ (ER+及/或PR+) / HER2-型)	FP-001 42 mg (6個月劑型)	二期臨床試驗啟動中		
	前列腺癌	FP-014 Triptorelin, 曲普瑞林			
FP-016 禾樹露	神經系統疾病				

資料來源：逸達；永豐投顧研究處整理，Jul. 2024

圖二：逸達 NCE 創新藥產品研發進程

作用機制	專案/產品	適應症	臨床前	一期臨床	二期臨床
MMP-12 抑制劑	FP-025 (aderamastat)	過敏性氣喘	臨床概念性驗證完成		
		心臟結節病 (Cardiac Sarcoidosis)、交感性腸病 (IBD)	臨床試驗規劃中		
	FP-020	氣喘或慢性阻塞性肺病 (Asthma or COPD)、特發性肺纖維化 (IPF)、間質性肺病 (ILD)	澳洲一期臨床試驗進行中		
ALDH2 活化劑	FP-045	范可尼貧血症 	臨床概念性驗證啟動中		
		間質性肺病引起的肺高壓 (PH-ILD) 	臨床概念性驗證申請準備中		
	FP-040	中樞神經系統疾病			

資料來源：逸達；永豐投顧研究處整理，Jul. 2024

逸達目前營收主要來自美國市場 Camcevi 六個月劑型銷售權利金之認列：逸達治療晚期前列腺癌藥物 Camcevi 相較市場競爭對手施打前必須透過人工混合藥劑，因逸達此藥已預先混和、預先充填，可避免醫護人員操作不順造成施打劑量誤差影響療效下，自 2Q22 年於美國市場上市後，銷量快速成長，2-4Q22、2023、1-5M24 銷量分別為 1,806、14,767 及 9,747 支，研究處預估 2024 年美國市場銷量可達 2.7 萬支(市佔率約 10%)，因公司美國市場營收認列為收取銷售權利金方式，加上歐盟地區年底前有機會核准上市，研究處預期將有約 850 萬美金里程碑金下，總計預估逸達 2024 年營收可達 4.59 億元(+135.2%YoY)。中國市場部分，因 Camcevi 42mg 註冊臨床試驗主要療效指標已達標，故 2H24 將由授權夥伴金賽藥業提出中國新藥查驗登記申請，預計 2026 年上市，而就目前市場注射主流劑型 Camcevi 21mg 三個月部分，也規劃於 2H24 進行美國藥證申請，2026 年上市。另在 FP-001 42mg 另一適應症兒童中樞性早熟部分，目前持續進行三期臨床試驗，預計 2025 年完成後將啟動國際授權，以 leuprolide 治療兒童中樞性早熟銷

售狀況來看，此藥在美國市場銷值約 3.8 億美金，參考公司 Camcevi 美國市場授權實績，倘若臨床數據結果佳，研究處推估授權金額有機會達 1~1.5 億美金。

**新藥開發部分：**因 MMP-12 在肺部疾病時會有過度表達現象，逸達以 MMP-12 抑制劑延伸開發系列藥物，其中，治療氣喘、慢性阻塞性肺病或特發性肺纖維化之 FP-020 預計今年底完成一期臨床試驗，針對發炎性腸道疾病包含克隆氏症、潰瘍性結腸炎等則在臨床試驗規畫中，心臟結節病藥 FP-025 預計 2H25 進行臨床二期；另因過度脂質氧化為導致肺動脈內皮平滑細胞異常增值原因，故氧化壓力清除劑 ALDH2 活化劑 Alda-1 已被用於肺高壓病變之研究，因逸達 FP-045 透過增加 ALDH2 活性可有更強之解醛毒能力，公司已於六月中向 US FDA 申請進行臨床二期試驗，預計年底開始執行，另在范可尼貧血症部分持續進行臨床二期中。

**財務預估：**預估逸達 2024 年營收 4.59 億元(+135.2%YoY)，毛利率 78%，稅後虧損 8.08 億元，稅後 EPS-5.94 元。

附表一：當年度損益表

單位：百萬元	24Q1	24Q2F	24Q3F	24Q4F	2024F
營業收入	104	98	112	144	459
營業毛利	41	41	101	137	358
營業利益	-135	-232	-219	-213	-799
稅前淨利	-108	-233	-221	-215	-777
稅後純益	-120	-240	-227	-221	-808
稅後 EPS (元)	-0.88	-1.77	-1.67	-1.63	-5.94
營收 QoQ 成長率	51.79	-4.85	14.29	28.57	--
營收 YoY 成長率	265.61	164.86	86.67	111.76	135.38
毛利率	39.47	41.84	90.18	95.14	78.00
營益率	-129.68	-236.73	-195.54	-147.92	-174.07
稅後純益率	-115.11	-244.90	-202.68	-153.47	-176.03

資料來源：CMoney；永豐投顧研究處整理，Jul. 2024

附表二：五個年度損益表

單位：百萬元	2020	2021	2022	2023	2024F
營業收入	230	226	302	195	459
%變動率	206.44	-1.91	33.39	-35.31	135.38
營業毛利	173	175	276	114	358
毛利率 (%)	75.26	77.46	91.53	58.44	78
營業淨利	-485	-539	-469	-1,008	-799
稅前淨利	-483	-528	-438	-989	-777
%變動率	--	--	--	--	--
稅後純益	-511	-569	-473	-1,036	-808
%變動率	--	--	--	--	--
稅後 EPS * (元)	-5.04	-4.85	-4	-8.14	-5.94
市調 EPS * (元)	-3.25	-3.86	-3.44	-6.16	0.53
PER (x)	--	--	--	--	--
PBR (x)	5.37	7.51	10.92	9.18	24.74
每股淨值 * (元)	15.65	11.20	7.70	9.16	3.4
每股股利 (元)	0.00	0.00	0.00	0.00	--
殖利率 (%)	--	--	--	--	--

\* 以目前股本計算

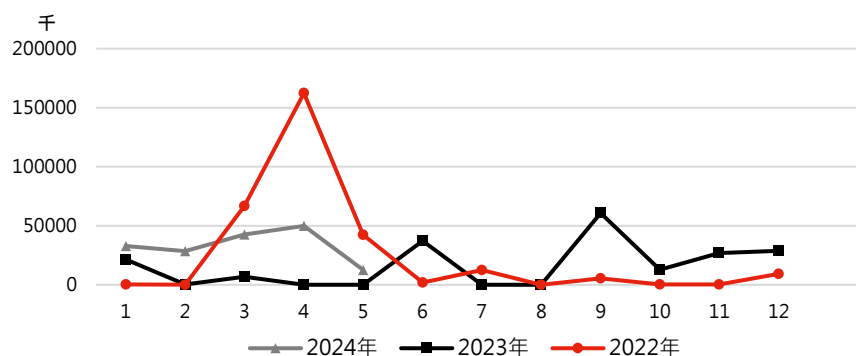
資料來源：CMoney；永豐投顧研究處整理，Jul. 2024

## 營運基本資料

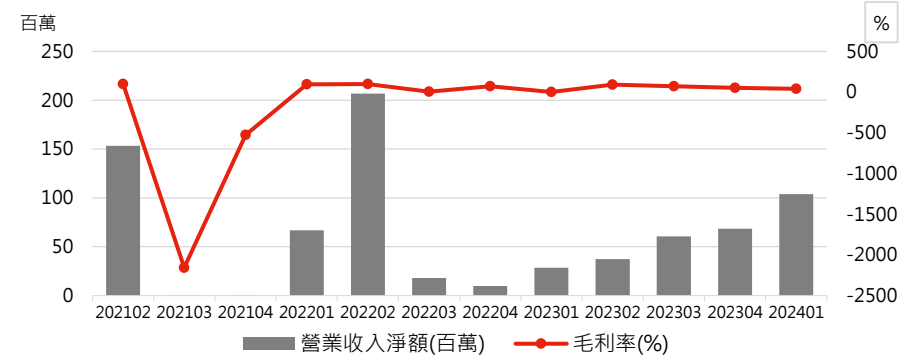
### 同業比較

代號	公司	投資建議	目前股價	市值(億)	稅後 EPS		PE		PB	
					2023	2024	2023	2024	2023	2024

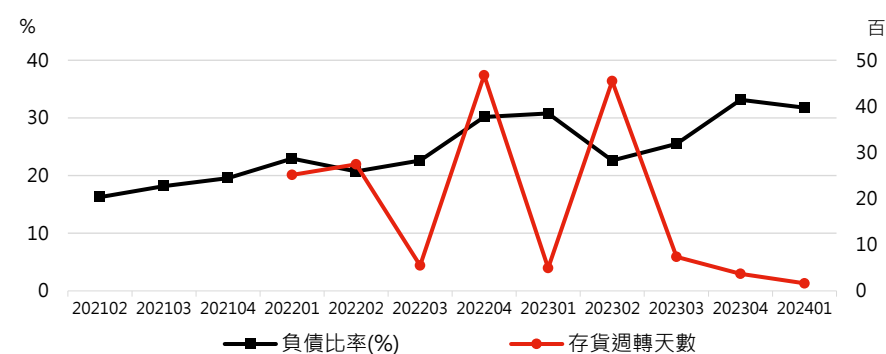
### 近三年單月營收狀況



### 近三年單季營收 VS 毛利率趨勢圖



### 負債比率 VS 存貨周轉天數



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110 年金管投顧新字第 024 號

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B：Buy 買進：未來 12 個月該股票表現將優於大盤

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S：Sell 賣出：未來 12 個月該股票表現將落後大盤

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