Biotech · Taiwan



EirGenix (6589.TWO/6589 TT)

Approval of EG12014 postponed

Outperform • Maintained Price as of September 15 (NT\$) 96.10 12M target price (NT\$) 135.0 Previous target price (NT\$) 164.0 Revised down (%) 17.7 Upside (%) 40.5

Key message

We maintain Outperform on EirGenix, but cut our target price to NT\$135 as the approval of EG12014 has been postponed to 3Q24 at the earliest, and as CDMO sales are declining in 2023.

Trading data			
Mkt cap (NT\$bn/US	29.38/	926	
Outstanding shares	305.8		
Foreign ownership	16.34		
3M avg. daily tradir	ng (mn)	1.07	
52-week trading ra	nge (NT\$)	91.30 -	158.5
Performance	3M	6M	12M
Absolute (%)	-11.4	-14.6	-18.2
Relative (%)	-9	-24.6	-33.5

Quarterly EPS

NT\$	1Q	2Q	3Q	4Q
2022	0.05A	0.02A	(0.09)A	(0.36)A
2023	(0.67)A	(0.64)A	(0.60)F	(0.52)F
2024	(0.65)F	0.21F	0.31F	1.23F



Even

EirGenix reported January-August sales of NT\$480mn, down 48.2% YoY, as CDMO (contract development and manufacturing organization) sales have declined markedly YTD, while the approval of EG12014, a biosimilar of Herceptin, has been pushed back, with the firm intending to apply for a drug license at end-2024, versus previous guidance of acquiring the license by end-2024. We now estimate the drug may be approved by 3Q24. As the results of EG1206A phase I trials were positive in May, the firm will proceed with licensing and prepare for phase III clinical trials in 3Q24. We expect the licensing of EG1206A to be completed by 2Q24.

Impact

CDMO sales declining, but capacity ramp-up continues. January-August sales fell 48.2% YoY to NT\$480mn as CDMO sales declined markedly, owing to the cancellation of COVID-19 vaccine orders (undiluted solution), and reduced investment in biodrugs from protein drug developers in the face of high inflation and interest rates. Going forward, EirGenix expects to increase the weighting of emerging biologics, including antibody-drug conjugates (ADC), multispecific antibodies, viral vectors, and cell therapy in its CDMO business. As for traditional biodrugs, the firm will invest heavily in manufacturing and microbial production systems. For reference, its mammal cell production capacity will reach 25.5k liters by the end of 3Q23F. The firm will also continue to invest in TFBS Bioscience (6939 TT, NT\$55, NR) to secure the source of key materials, such as viral vectors for cell/gene therapies. The launch of TFBS Bioscience's plasmid DNA production platform is scheduled for 4Q23.

Approval of EG12014 postponed again. EirGenix met with the US FDA on June 23 to report improvements made by the contract manufacturing partner for freeze-dried filling to meet FDA requirements. Three validation batches are undergoing the second batch, with expected completion for revalidated production in November. The resubmission date has been extended to the end of this year, and approval is now anticipated in 3Q24F. However, due to the presence of six Herceptin biosimilar drugs already on the market, entering the market later may be less advantageous in terms of pricing. Taiwan's FDA approved EG12014 license in May and is planning to start sales in October. The company expects approval from the European Medicines Agency (EMA) in 4Q23.

Valuation & Action

We maintain Outperform on EirGenix with a target price of NT\$135 via the discounted cash flow method, with an 11% discount rate that factors in risk adjustments between 2023 and 2033.

Risks

Resubmission delay again of EG12014.

Key financials and valuations					
	Dec-20A	Dec-21A	Dec-22A	Dec-23F	Dec-24F
Revenue (NT\$mn)	1,072	1,697	1,481	800	2,286
Gross profit (NT\$mn)	751	1,093	756	168	1,542
Operating profit (NT\$mn)	(986)	(58)	(331)	(846)	434
Net profit (NT\$mn)	(1,042)	(43)	(116)	(738)	332
EPS (NT\$)	(5.41)	(0.18)	(0.38)	(2.42)	1.09
Cash DPS (NT\$)	-	-	-	-	-
EPS growth (%)	0.3	(96.8)	117.1	536.3	0.0
PE (x)	N.A.	N.A.	N.A.	N.A.	88.1
PB (x)	10.4	2.8	2.7	2.9	2.8
EV/EBITDA (x)	N.A.	142.3	N.A.	N.A.	36.2
Net debt to equity (%)	5.3	Net cash	Net cash	Net cash	Net cash
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Return on average equity (%)	(55.4)	(0.7)	(1.1)	(7.2)	3.3

Source: Company data, KGI Research estimates

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EG1206A expected to be licensed out by 2Q24F. Due to satisfactory pharmacokinetic results of EG1206A in phase I clinical trials, management intends to launch phase III clinical trials in 3Q24, and licensing could be concluded by 2Q24. We estimate the value of the licensing deal will be higher than that of EG12014. EG1206A is the biosimilar of Perjeta and creates synergies when used with Herceptin. Dual-target therapy (Perjeta+Herceptin) has been confirmed by Roche (CH) to be the most effective first-line treatment for HER2-positive metastatic breast cancer. The combo of EG12014 and EG1206A may boost sales for EG12014 when it's launched, and could offset pricing competition from other Herceptin biosimilars.

Figure 1: Breakdown of 3Q-4Q23 forecast revisions

	3Q23F				4Q23F				.	
NT\$mn	Revision	Previous	Chg. (%)	QoQ (%)	YoY (%)	Revision	Previous	Chg. (%)	QoQ (%)	YoY (%)
Sales	168	358	(53.0)	(50.0)	(53.5)	277	392	(29.3)	64.7	(34.2)
Gross profits	50	185	(72.8)	(65.5)	(67.0)	97	213	(54.4)	92.2	(54.1)
Operating income	(212)	(77)	-	=	-	(157)	(42)	-	-	=
Net income	(182)	(23)	-	=	-	(158)	1	-	-	=
EPS (NT\$)	(0.60)	(80.0)	-	-	-	(0.52)	0.00	-	-	-
Gross margin (%)	30.0	51.8	(21.8)ppts	(13.5)ppts	(12.3)ppts	35.0	54.3	(19.3)ppts	5.0 ppts	(15.2)ppts
OP margin (%)	(125.8)	(21.4)	(104.4)ppts	(100.4)ppts	(86.6)ppts	(56.8)	(10.6)	(46.2)ppts	69.0 ppts	(40.6)ppts
Net margin (%)	(108.1)	(6.4)	(101.7)ppts	(110.0)ppts	(100.4)ppts	(57.1)	0.4	(57.5)ppts	50.9 ppts	(31.4)ppts

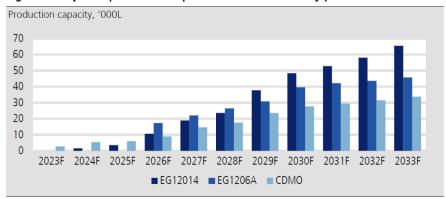
Source: Bloomberg; KGI Research estimates

Figure 2: Breakdown of 2023-24 forecast revisions

	2023F				2024F			
NT\$mn	Revision	Previous	Diff. (%)	YoY (%)	Revision	Previous	Chg. (%)	YoY (%)
Sales	800	1,402	(42.9)	(46.0)	2,286	3,255	(29.7)	185.8
Gross profit	168	716	(76.5)	(77.8)	1,542	2,586	(40.3)	816.6
Operating income	(846)	(321)	-	-	434	1,477	(70.6)	-
Net income	(738)	(127)	-	-	332	1,371	(75.8)	-
EPS (NT\$)	(2.42)	(0.42)	-	-	1.09	4.56	(75.8)	-
Gross margin (%)	21.0	51.1	(30.0)ppts	(30.0)ppts	67.5	79.5	(12.0)ppts	46.4 ppts
OP margin (%)	(105.7)	(22.9)	(82.8)ppts	(83.3)ppts	19.0	45.4	(26.4)ppts	124.7 ppts
Net margin (%)	(92.2)	(9.1)	(83.1)ppts	(84.4)ppts	14.5	42.1	(27.6)ppts	106.7 ppts

Source: Bloomberg; KGI Research estimates

Figure 3: Projected production capacities of three mainstay products

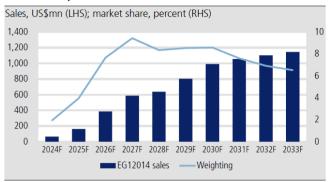


Source: Company data; KGI estimates

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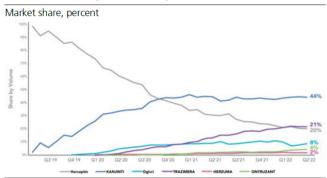


Figure 4: Projected sales of EG12014 & market share versus other Herceptin biosimilars



Source: KGI estimates

Figure 6: Market share of brand name drug Herceptin has declined markedly due to competition from biosimilars



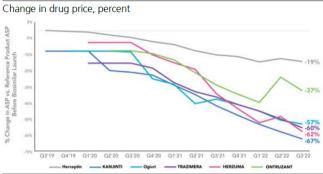
Source: Amgen 2022 biosimilar trends report

Figure 5: Projected sales & market share of EG1206A



Source: KGI estimates

Figure 7: Through bundle sales, Roche has kept prices of Herceptin afloat despite competition from biosimilars



Source: Amgen 2022 biosimilar trends report

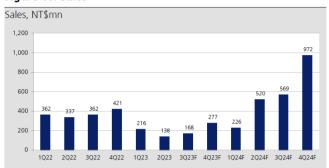


Figure 8: Company profile

EirGenix was established on December 21, 2012. It is mainly engaged in Contract Development and Manufacturing Organization (CDMO) service of biopharmaceuticals and biosimilar. EirGenix currently has a total of 7 drugs under development, which can be divided into three main axes, of which 4 are biological drugs for treating HER2 gene mutations in breast cancer, 2 are biological drugs that inhibit angiogenesis, and 1 is a carrier protein for vaccines.

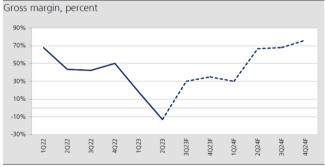
Source: KGI Research

Figure 10: Sales



Source: KGI Research

Figure 12: Gross Margin



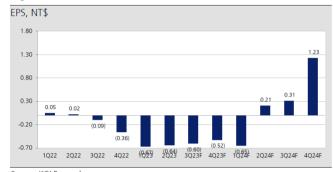
Source: KGI Research

Figure 9: Revenue



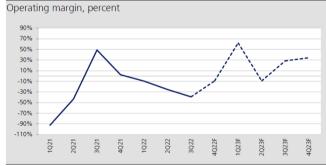
Source: Company data; KGI Research

Figure 11: EPS



Source: KGI Research

Figure 13: Operating Margin



Source: KGI Research



Income statement	Quarterly								Annually		
		Jun-23A	Sen_23F	Dec-23F	Mar-24F	lun-24F	Sen-24F	Dec-24F	,	Dec-23F	Dec-24F
Income statement (NT\$mn)	101a1 - 2574	Juli 25/1	3cp-23i	DCC 251	11101-2-1	Juli 241	3cp-2-4	DCC 2-41	DCC 22/1	DCC-251	DCC-241
Revenue	216	138	168	277	226	520	569	972	1,481	800	2,286
Cost of goods sold	(178)	(156)	(118)	(180)	(158)	(173)	(182)	(231)	(725)	(632)	(744)
Gross profit	39	(18)	50	97	68	347	387	741	756	168	1,542
Operating expenses	(259)	(238)	(262)	(255)	(275)	(277)	(279)	(277)	(1,087)	(1,014)	(1,108)
Operating profit	(220)	(256)	(212)	(157)	(207)	70	108	464	(331)	(846)	434
Depreciation of fixed assets	(53)	(55)	(43)	(22)	(44)	(44)	(44)	(44)	(189)	(172)	(175)
Amortisation of intangible assets	(5)	(3)	(5)	(7)	(5)	(5)	(5)	(5)	(16)	(172)	(19)
EBITDA	(163)	(198)	(164)	(129)	(1 59)	118	1 56	512	(126)	(654)	628
Interest income	31	(190)	(104)	(8)	(133)	110	150	-	60	31	020
Investment income	31	-	0	(0)	=	=	=	=	00	31	=
Other non-op income	0	33	11	-	-	_	-	_	38	- 45	-
•				- (0)	-	-	-		97		-
Non-operating income	31	33	19	(8)	- (2)	- (2)	- (2)	- (4)		75	- /11)
Interest expense	(2)	(3)	(3)	(4)	(2)	(2)	(3)	(4)	(10)	(12)	(11)
Investment loss	- (11)	-	- 1.4	- 11	- 13	- 13	- 12		120	- 4F	- 44
Other non-op expenses	(11)	32	14	11	13	12	12	7	129	45	44
Non-operating expenses	(14)	29	11	7	10	10	10	3	119	33	33
Pre-tax profit	(203)	(194)	(182)	(158)	(197)	80	118	467	(114)	(737)	467
Current taxation	(0)	(0)	-	-	-	(17)	(24)	(94)	(1)	(1)	(136)
Minorities	-	-	-	-	-	-	-	-	- (446)	- (720)	-
Normalised net profit	(203)	(194)	(182)	(158)	(197)	63	93	373	(116)	(738)	332
Extraordinary items	(0)	0	-	-	-	-	-	-	-	0	-
Net profit	(203)	(194)	(182)	(158)	(197)	63	93	373	(116)	(738)	332
EPS (NT\$)	(0.67)	(0.64)	(0.60)	(0.52)	(0.65)	0.21	0.31	1.23	(0.38)	(2.42)	1.09
Margins (%)	47.0	(42.0)	20.0	25.0	20.0	66.7	60.0	76.2	F4.4	24.0	67.5
Gross profit margin	17.9	(13.0)	30.0	35.0	30.0	66.7	68.0	76.2	51.1	21.0	67.5
Operating margin	(101.9)	(185.0)	(125.8)	(56.8)	(91.9)	13.4	19.0	47.7	(22.3)	(105.7)	19.0
EBITDA margin	(75.3)	(143.4)	(97.3)	(46.6)	(70.4)	22.7	27.5	52.7	(8.5)	(81.7)	27.5
Pretax profit margin	(93.9)	(140.0)	(108.1)	(57.1)	(87.3)	15.3	20.7	48.1	(7.7)	(92.1)	20.4
Net profit margin	(94.1)	(140.3)	(108.1)	(57.1)	(87.3)	12.1	16.4	38.4	(7.8)	(92.2)	14.5
Sequential growth (%)											
Revenue growth	(48.7)	(36.1)	21.7	64.7	(18.6)	130.4	9.3	70.9			
Gross profit growth	(81.7)	(146.4)		92.2	(30.3)	413.5	11.4	91.6			
Operating profit growth	222.2	16.1	(17.3)	(25.6)	31.6		54.9	329.6			
EBITDA growth	1102.7	21.8	(17.4)	(21.2)	23.0		32.4	227.5			
Pretax profit growth	87.9	(4.7)	(6.1)	(12.9)	24.4		48.1	296.5			
Net profit growth	88.0	(4.6)	(6.3)	(12.9)	24.4		48.9	299.3			
YoY growth (%)											
Revenue growth	(40.2)	(58.9)	(53.5)	(34.2)	4.3	276.0	238.0	250.6	(12.7)	(46.0)	185.8
Gross profit growth	(84.2)	(112.3)	(67.0)	(54.1)	74.3		666.3	663.7	(30.8)	(77.8)	816.6
Operating profit growth	526.4	199.5	49.3	130.2	(6.0)				467.3	155.6	
EBITDA growth	(1357.8)	457.4	83.3	853.0	(2.5)				(199.1)	421.0	
Pretax profit growth	(1532.1)	(2953.1)	569.5	46.5	(3.0)				177.7	544.7	
Net profit growth	(1569.0)	(3123.6)	559.6	46.3	(3.2)				171.3	538.5	

Source: Company data, KGI Research estimates



Balance sheet					
NTSmn	Dec-20A	Dec-21A	Dec-22A	Dec-23F	Dec-24F
Total assets	3,835	11,441	11,847	11,092	11,445
Current assets	1,494	9,070	8,288	7,439	7,650
Cash & ST securities	1,023	8,263	7,127	6,388	6,454
Inventory	161	414	739	645	757
Accounts receivable	94	80	33	18	50
Other current assets	217	313	389	389	389
Non-current assets	2,341	2,371	3,559	3,653	3,794
LT investments	14	20	382	392	407
Net fixed assets	1,852	1,887	2,609	2,693	2,819
Other assets	475	464	569	569	569
Total liabilities	1,930	1,012	1,164	1,147	1,168
Current liabilities	642	703	731	754	761
Accounts payable	41	86	135	117	138
Interest bearing ST liabilities	91	127	-	40	27
Other current liabilities	510	490	596	596	596
Non-current liabilities	1,287	309	433	393	407
Long-term debt	918	-	120	80	94
Other L-T liabilities	65	21	1	1	1
Total equity	1,906	10,429	10,683	9,945	10,277
Share capital	2,064	3,004	3,043	3,043	3,043
Retained earnings reserve	(2,931)	(2,974)	(116)	(853)	(521)
Minority interests	-	-	-	-	-
Preferred shareholders funds	-	-	-	-	-

	Dec-20A	Dec-21A	Dec-22A	Dec-23F	Dec-24F
Growth					
Revenue growth	125.1%	58.4%	(12.7%)	(46.0%)	185.8%
Operating profit growth	16.3%	(94.1%)	467.3%	155.6%	
EBITDA growth	10.9%		(199.1%)	421.0%	
Net profit growth	21.0%	(95.9%)	171.3%	538.5%	
EPS growth	0.3%	(96.8%)	117.1%	536.3%	
Profitability					
Gross profit margin	70.0%	64.4%	51.1%	21.0%	67.5%
Operating margin	(92.0%)	(3.4%)	(22.3%)	(105.7%)	19.0%
EBITDA margin	(75.9%)	7.5%	(8.5%)	(81.7%)	27.5%
Net profit margin	(97.2%)	(2.5%)	(7.8%)	(92.2%)	14.5%
Return on average assets	(28.7%)	(0.6%)	(1.0%)	(6.4%)	2.9%
Return on average equity	(55.4%)	(0.7%)	(1.1%)	(7.2%)	3.3%
Stability					
Gross debt to equity	52.9%	1.2%	1.1%	1.2%	1.2%
Net debt to equity	5.3%	Net cash	Net cash	Net cash	Net cash
Interest coverage (x)	(35.5)	(0.9)	(10.9)	(62.1)	43.2
Interest & ST debt coverage (x)	1.1	(0.7)	1.1	1.1	0.9
Cash flow interest coverage(x)	(14.7)	(1.4)	(15.3)	(38.8)	36.2
Cash flow/int. & ST debt (x)	(3.5)	(0.2)	(15.3)	(8.8)	10.6
Current ratio (x)	2.3	12.9	11.3	9.9	10.1
Quick ratio (x)	2.1	12.3	10.3	9.0	9.1
Net debt (NT\$mn)	100	(6,498)	(6,006)	(5,267)	(5,333)
Per share data					
EPS (NT\$)	(5.41)	(0.18)	(0.38)	(2.42)	1.09
CFPS (NT\$)	(2.18)	(0.12)	(0.49)	(1.49)	1.32
BVPS (NT\$)	9.23	34.72	35.10	32.68	33.77
Adj BVPS (NT\$)	9.90	42.98	35.23	32.68	33.77
SPS (NT\$)	5.57	6.99	4.88	2.63	7.51
EBITDA/share (NT\$)	(4.23)	0.52	(0.41)	(2.15)	2.06
Cash DPS (NT\$)	-	-	-	-	-
Activity					
Sales / avg assets	0.30	0.22	0.13	0.07	0.20
Days receivable	32.0	17.2	8.1	8.1	8.1
Days inventory	183.4	249.9	372.5	372.5	372.5
Days payable	46.9	52.2	67.8	67.8	67.8
Cash cycle	168.4	214.9	312.8	312.8	312.8

Source: Company data, KGI Research estimates

Profit & loss					
NT\$mn	Dec-20A	Dec-21A	Dec-22A	Dec-23F	Dec-24F
Revenue	1,072	1,697	1,481	800	2,286
Cost of goods sold	(321)	(604)	(725)	(632)	(744)
Gross profit	751	1,093	756	168	1,542
Operating expenses	(1,737)	(1,151)	(1,087)	(1,014)	(1,108)
Operating profit	(986)	(58)	(331)	(846)	434
Non-operating income	5	51	97	75	-
Interest income	3	10	60	31	-
Investment income	-	-	-	-	-
Other non-op income	2	40	38	45	-
Non-operating expenses	(60)	(33)	119	33	33
Interest expense	(29)	(21)	(10)	(12)	(11)
Investment loss	-	-	-	-	-
Other non-op expenses	(31)	(12)	129	45	44
Pre-tax profit	(1,041)	(41)	(114)	(737)	467
Current taxation	(0)	(1)	(1)	(1)	(136)
Minorities	-	-	-	-	_
Extraordinary items	-	0	(0)	0	-
Net profit	(1,042)	(43)	(116)	(738)	332
EBITDA	(814)	127	(126)	(654)	628
EPS (NT\$)	(5.41)	(0.18)	(0.38)	(2.42)	1.09

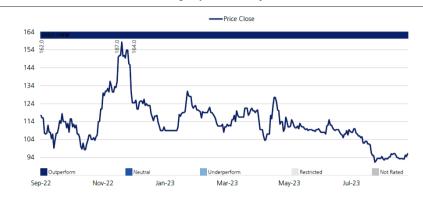
Cash flow					
NTSmn	Dec-20A	Dec-21A	Dec-22A	Dec-23F	Dec-24F
Operations cash flow	(419)	(30)	(148)	(454)	401
Net profit	(1,042)	(43)	(116)	(738)	332
Depreciation & amortisation	172	185	205	191	194
Decrease in working capital	105	(194)	(228)	92	(125)
Other operating cash flow	345	22	(9)	(0)	-
Investing cash flow	(228)	(1,757)	(476)	(285)	(335)
Sale of ST investment	(111)	(1,523)	337	-	-
New investments	-	-	(20)	(10)	(15)
Capital expenditure	(38)	(167)	(346)	(256)	(301)
Others investing cashflow	(79)	(67)	(447)	(19)	(19)
Free cash flow	(761)	(252)	(719)	(838)	57
Financing cash flow	1,264	7,504	125	-	(0)
Increase in short term debt	-	-	-		
Increase in long term loans	259	(718)	120	-	-
New ordinary shares issued	1,012	8,230	-		
Ordinary dividends paid	=	-	-	-	-
Other financing cashflow	(8)	(8)	5	_	(0)
Forex effects	0	(0)	0		
Total cash generated	616	5,717	(498)	(739)	66

ROIC					
	Dec-20A	Dec-21A	Dec-22A	Dec-23F	Dec-24F
1 - COGS/revenue					
- Operating exp./revenue	162.0%	67.8%	73.4%	126.7%	48.5%
= Operating margin	(92.0%)	(3.4%)	(22.3%)	(105.7%)	19.0%
1 / (Working capital/revenue	(0.1)	0.1	0.3	0.4	0.2
+ Net PPE/revenue	1.7	1.1	1.8	3.4	1.2
+ Other assets/revenue)	0.1	0.1	0.1	0.3	0.1
= Capital turnover	0.6	0.7	0.5	0.2	0.7
Operating margin	(92.0%)	(3.4%)	(22.3%)	(105.7%)	19.0%
x Capital turnover	0.6	0.7	0.5	0.2	0.7
x (1 - tax rate)	100.0%	103.4%	101.1%	100.1%	71.0%
= After-tax ROIC	(52.0%)	(2.7%)	(10.3%)	(26.1%)	8.8%

Source: Company data, KGI Research estimates



EirGenix - Recommendation & target price history



Date	Rating	Target	Price
2023-03-15	Outperform	164.0	112.5
2022-12-16	Outperform	164.0	124.5
2022-11-29	Outperform	187.0	133.0
2021-11-29	Outperform	162.0	109.0
2021-08-05	Outperform	156.0	133.5
2021-08-05	Outperform	156.0	133.5
2021-04-12	Neutral	119.0	160.0
2021-03-24	Outperform	119.0	106.5
2020-12-24	Outperform	67.0	47.4

Source: TEJ, KGI Research

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