

Kelun-Biotech (6990 HK)

Innovative bispecific ADC product licensed to MSD

Kelun-Biotech recorded RMB1.38bn (+32% YoY) revenue in 1H24, including a total of US\$90mn (or RMB641mn) milestone payments from MSD regarding multiple collaborated pipelines. In 1H24, Kelun-Biotech spent RMB652mn on R&D, +33% YoY, mainly driven by an uptick in clinical trials. The company is gearing up for the near-term launch of several key assets in China, including sac-TMT (TROP2 ADC), A166 (HER2 ADC), A167 (PD-L1 mAb) and A140 (cetuximab biosimilar) in 2H24 or 1H25. In preparation, the company has assembled a commercial team of 110+ people, with plans to expand the salesforce to around 400 employees by end-2024. Therefore, in 1H24, the company recorded RMB41mn in selling expenses (vs 0 in 1H23). Kelun-Biotech achieved RMB310mn net profit in 1H24. The company received RMB492mn in net proceeds from the placement of new H shares in May 2024. As of Jun 2024, Kelun-Biotech had a robust cash balance (incl. financial assets) of RMB2.9bn. Following Kelun Pharma's subscription to new domestic shares, the company expects to receive an additional RMB601mn in net proceeds.

- **The second BLA of sac-TMT submitted in China.** Following the BLA submission of sac-TMT for 3L+ TNBC in Nov 2023, Kelun-Biotech recently submitted the second BLA of sac-TMT for 3L+ post-chemo and TKI-resistant EGFRm NSCLC in Aug 2024. Concurrently, Kelun-Biotech is preparing another BLA submission for sac-TMT for the treatment of 2L TKI-resistant EGFRm NSCLC. For EGFR-wild type NSCLC, the company has initiated a Ph3 trial in China to compare sac-TMT + Keytruda vs Keytruda in 1L PD-L1+ (TPS $\geq$ 1%) NSCLC. Additionally, the CDE has granted approval for a Ph3 study of sac-TMT + Keytruda for first-line PD-L1-negative (TPS<1%) nsq-NSCLC, with the FPI expected soon. It's noteworthy that sac-TMT (Q3W) + A167 (PD-L1 mAb) achieved 15.4 months of mPFS in 1L NSCLC in a Ph2 study, significantly surpassing the SoC and other TROP2 ADC competitors (*CMBI report link*).
- **Out-licensed innovative bispecific ADC to MSD.** MSD has initiated 10 global Ph3 trials of sac-TMT. These trials encompass a range of indications including NSCLC with five trials, TNBC, HR+/HER2- BC, GC, EC, and CC. The broad spectrum of clinical trials underscores MSD's commitment to advance sac-TMT's development. We expect MSD to initiate additional Ph3 trials of sac-TMT. MSD has exercised its option to in-license the ex-China rights of SKB571, a novel bispecific ADC at IND-enabling stage targeting lung and gastrointestinal tumors. For this, MSD will make an exercise payment of US\$37.5mn to Kelun-Biotech, in addition to future milestone and royalty payments. Concurrently, MSD has returned the global rights for SKB315 (CLDN18.2 ADC) to Kelun-Biotech which will continue its development in China. Additionally, MSD/Kelun-Biotech are investigating SKB410/MK-3120 (Nectin4 ADC) in Ph1a study. Kelun-Biotech plans to submit IND applications for other four preclinical ADC assets under its licensed collaboration with MSD soon, and to explore new collaboration opportunities with MSD.
- **Maintain BUY.** We remain confident about SKB264's global development and the approval in China. We raise our DCF-based TP from HK\$246.13 to HK\$243.38 (WACC: 10.31%, terminal growth rate: 4.0%).

Earnings Summary

(YE 31 Dec)	FY22A	FY23A	FY24E	FY25E	FY26E
Revenue (RMB mn)	804	1,540	1,809	1,028	1,598
YoY growth (%)	2,387	92	17	(43)	56
Net profit (RMB mn)	(616)	(574)	(226)	(964)	(931)
EPS (Reported) (RMB)	(5.74)	(2.84)	(1.01)	(4.32)	(4.18)
R&D expenses (RMB mn)	(846)	(1,031)	(1,370)	(1,438)	(1,510)
Admin expenses (RMB mn)	(95)	(182)	(140)	(168)	(202)
CAPEX (RMB mn)	(34)	(81)	(100)	(150)	(150)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	HK\$243.38
(Previous TP)	HK\$246.13)
Up/Downside	44.6%
Current Price	HK\$168.30

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Stock Data

Mkt Cap (HK\$ mn)	37,504.7
Avg 3 mths t/o (HK\$ mn)	64.4
52w High/Low (HK\$)	189.30/72.05
Total Issued Shares (mn)	222.8
Source: FactSet	

Shareholding Structure

Kelun Pharma	68.5%
MSD	6.1%

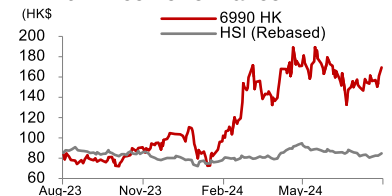
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	13.2%	12.6%
3-mth	-1.6%	10.4%
6-mth	64.7%	52.8%

Source: FactSet

12-mth Price Performance



Source: FactSet

Figure 1: SKB264's Ph3 trials conducted by MSD (as of Aug 2024)

Indication	Indication details	Trial ID	Regimen	SKB264 dose	Primary endpoint	Start date	Primary completion date (est)
3L+ EGFR-m NSCLC	Previously treated nsq-NSCLC with EGFR mutations or other genomic alterations (ALK, ROS1, BRAF, NTRK, MET, RET, etc) (pre-treated with TKI, and chemo)	NCT06 074588	Mono vs chemo (docetaxel or pemetrexed)	Q2W	PFS, OS	Nov 2023	May 2027
2L EGFR-m NSCLC	post EGFR-TKI nsq-NSCLC (pre-treated with TKI)	NCT06 305754	Mono vs chemo (pemetrexed + carboplatin)	Q2W	PFS, OS	Jun 2024	Sep 2028
1L sq-NSCLC	Maintenance treatment for 1L sq-NSCLC (pts have 4 cycles of prior Keytruda+chemo treatment)	NCT06 422143	SKB264+Keytruda vs Keytruda	Q2W	OS	Jun 2024	Jan 2029
1L NSCLC TPS ≥50%	1L PD-L1 TPS ≥50% NSCLC	NCT06 170788	+ Keytruda vs Keytruda mono	Q2W	OS	Dec 2023	Jan 2028
Adjuvant NSCLC	Adjuvant NSCLC (Stage II, IIIA, IIIB resectable NSCLC not achieving pCR)	NCT06 312137	SKB264+Keytruda vs Keytruda	Q2W	DFS	Apr 2024	Feb 2034
Endometrial carcinoma	Endometrial carcinoma (post chemo and PD(L)-1)	NCT06 132958	Mono vs chemo	Q2W	PFS, OS	Dec 2023	Jan 2028
HR+/HER2- BC	HR+/HER2- BC (post endocrine therapies with one in combo with a CDK4/6 inhibitor)	NCT06 312176	SKB264 mono vs SKB264+Keytruda vs chemo	Q2W	PFS	Apr 2024	Jul 2027
TNBC	TNBC (who received neoadjuvant therapy and did not achieve pCR at surgery)	NCT06 393374	SKB264+Keytruda vs Keytruda mono or Keytruda + capecitabine	Q2W	iDFS (invasive disease-free survival)	Jun 2024	Dec 2030
3L+ GC	3L+ GC	NCT06 356311	Mono vs chemo	Q2W	OS	May 2024	Jan 2027
2L RR CC	Recurrent or Metastatic Cervical Cancer	NCT06 459180	Mono vs chemo	Q2W	OS	Jul 2024	Oct 2028

Source: Company data, CMBIGM.

Figure 2: Risk-adjusted DCF valuation

DCF Valuation (RMB mn)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	-154	-977	-911	-82	1,548	3,049	4,399	5,844	7,123	7,963	8,310	8,198
Tax rate	0%	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	-154	-977	-911	-82	1,316	2,592	3,739	4,967	6,054	6,769	7,063	6,968
+ D&A	30	36	41	47	54	56	58	60	61	63	65	66
- Change in working capital	-633	-89	-149	-340	-251	-259	-200	-104	-21	33	85	80
- Capex	-100	-150	-150	-200	-200	-100	-100	-100	-100	-100	-100	-100
FCFF	-856	-1,181	-1,170	-575	919	2,289	3,497	4,823	5,995	6,765	7,113	7,014
Terminal value												115,674
FCF + terminal value	-856	-1,181	-1,170	-575	919	2,289	3,497	4,823	5,995	6,765	7,113	122,688

Present value of enterprise (RMB mn) 48,031

Net debt (RMB mn) -1,324

Equity value (RMB mn) 49,356

No. of shares (mn) 223

DCF per share (RMB) 221.48

DCF per share (HK\$) 243.38

Terminal growth rate 4.0%

WACC 10.31%

Cost of equity 14.0%

Cost of debt 4.0%

Equity beta 1.05

Risk-free rate 3.0%

Market risk premium 10.5%

Target debt to asset ratio 35.0%

Effective corporate tax rate 15.0%

Source: CMBIGM estimates

Figure 3: Sensitivity analysis (HK\$)

Terminal growth rate	WACC				
	9.31%	9.81%	10.31%	10.81%	11.31%
5.0%	363.80	316.58	278.52	247.26	221.17
4.5%	332.40	292.34	259.44	231.98	208.76
4.0%	306.92	272.28	243.38	218.95	198.06
3.5%	285.83	255.41	229.69	207.70	188.73
3.0%	268.08	241.01	217.87	197.90	180.52

Source: CMBIGM estimates

Figure 4: CMBIGM estimates revision

RMB mn	New			Old			Diff (%)		
	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E
Revenue	1,809	1,028	1,598	918	1,079	1,638	97%	-5%	-3%
Gross profit	1,446	835	1,314	645	819	1,346	124%	2%	-3%
Operating profit	-124	-961	-898	-656	-772	-687	NA	NA	NA
Net profit	-226	-964	-931	-659	-786	-727	NA	NA	NA
EPS (RMB)	(1.01)	(4.32)	(4.18)	(3.01)	(3.59)	(3.31)	NA	NA	NA
Gross margin	79.97%	81.27%	82.22%	70.24%	75.92%	82.17%	+9.73 ppt	+5.34 ppt	+0.06 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Figure 5: CMBIGM estimates vs consensus

RMB mn	CMBIGM			Consensus			Diff (%)		
	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E
Revenue	1,809	1,028	1,598	1,384	1,489	2,367	31%	-31%	-32%
Gross profit	1,446	835	1,314	899	1,114	1,823	61%	-25%	-28%
Operating profit	-124	-961	-898	-494	-687	-291	NA	NA	NA
Net profit	-226	-964	-931	-536	-696	-359	NA	NA	NA
EPS (RMB)	(1.01)	(4.32)	(4.18)	(2.12)	(2.96)	(1.45)	NA	NA	NA
Gross margin	79.97%	81.27%	82.22%	64.99%	74.82%	77.00%	+14.98 ppt	+6.45 ppt	+5.22 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Revenue	32	804	1,540	1,809	1,028	1,598
Cost of goods sold	(21)	(277)	(781)	(362)	(193)	(284)
Gross profit	12	527	759	1,446	835	1,314
Operating expenses	(789)	(946)	(1,143)	(1,570)	(1,796)	(2,212)
Selling expense	0	0	(20)	(110)	(226)	(533)
Admin expense	(96)	(95)	(182)	(140)	(168)	(202)
R&D expense	(728)	(846)	(1,031)	(1,370)	(1,438)	(1,510)
Others	35	(4)	90	50	37	33
Operating profit	(777)	(419)	(383)	(124)	(961)	(898)
Net Interest income/(expense)	(113)	(149)	(84)	(3)	(3)	(33)
Pre-tax profit	(890)	(567)	(468)	(127)	(964)	(931)
Income tax	0	(49)	(106)	(99)	0	0
After tax profit	(890)	(616)	(574)	(226)	(964)	(931)
Minority interest	0	0	0	0	0	0
Net profit	(890)	(616)	(574)	(226)	(964)	(931)

BALANCE SHEET	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Current assets	298	332	2,807	2,791	1,628	1,895
Cash & equivalents	82	93	1,529	1,344	777	888
Restricted cash	37	26	40	40	40	40
Account receivables	79	99	215	7	61	209
Inventories	79	53	63	89	40	47
Financial assets at FVTPL	0	0	634	934	334	334
Other current assets	23	62	327	377	377	377
Non-current assets	515	661	702	772	886	996
PP&E	432	530	608	677	792	901
Right-of-use assets	42	117	85	85	85	85
Intangibles	0	3	1	1	1	1
Other non-current assets	40	10	8	8	8	8
Total assets	813	993	3,510	3,563	2,514	2,890
Current liabilities	3,445	4,167	1,110	295	210	1,517
Short-term borrowings	2,388	2,891	0	0	0	1,300
Account payables	185	243	523	148	63	69
Other current liabilities	761	787	21	21	21	21
Lease liabilities	2	82	54	54	54	54
Contract liabilities	109	164	511	72	72	72
Non-current liabilities	12	52	70	70	70	70
Deferred income	11	11	65	65	65	65
Other non-current liabilities	1	41	6	6	6	6
Total liabilities	3,457	4,219	1,180	366	280	1,587
Share capital	107	107	219	219	219	219
Other reserves	(2,751)	(3,334)	2,110	2,978	2,015	1,084
Total shareholders equity	(2,644)	(3,226)	2,329	3,198	2,234	1,303
Total equity and liabilities	813	993	3,510	3,563	2,514	2,890

CASH FLOW	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	(890)	(567)	(468)	(127)	(964)	(931)
Depreciation & amortization	23	67	75	30	36	41
Tax paid	0	(49)	0	(99)	0	0
Change in working capital	279	35	276	(633)	(89)	(149)
Others	102	195	177	3	3	33
Net cash from operations	(486)	(320)	60	(826)	(1,015)	(1,007)
Investing						
Capital expenditure	(94)	(34)	(81)	(100)	(150)	(150)
Net proceeds from disposal of short-term investments	0	1	(623)	(300)	600	0
Others	(1)	1	(321)	(50)	0	0
Net cash from investing	(94)	(32)	(1,025)	(450)	450	(150)
Financing						
Dividend paid	0	0	0	0	0	0
Net borrowings	155	318	(394)	0	0	1,300
Proceeds from share issues	534	0	1,482	1,094	0	0
Others	(42)	(5)	1,294	(3)	(3)	(33)
Net cash from financing	647	313	2,382	1,091	(3)	1,267
Net change in cash						
Cash at the beginning of the year	16	82	93	1,529	1,344	777
Exchange difference	(1)	1	19	0	0	0
Cash at the end of the year	82	44	1,529	1,344	777	888
GROWTH	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
Revenue	na	2,387.3%	91.6%	17.4%	(43.2%)	55.5%
Gross profit	na	4,368.1%	44.0%	90.5%	(42.2%)	57.3%
PROFITABILITY	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
Gross profit margin	36.5%	65.6%	49.3%	80.0%	81.3%	82.2%
Operating margin	(2,404.6%)	(52.1%)	(24.9%)	(6.9%)	(93.5%)	(56.2%)
Return on equity (ROE)	na	na	na	(8.2%)	(35.5%)	(52.6%)
GEARING/LIQUIDITY/ACTIVITIES	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
Current ratio (x)	0.1	0.1	2.5	9.5	7.7	1.2
VALUATION	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
P/E	ns	ns	ns	ns	ns	ns
P/B	ns	ns	12.2	10.7	15.4	26.4

Source: Company data, CMBIGM estimates. Note: The calculation of net cash includes financial assets.

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