

Kelun-Biotech (6990 HK)

Intense data release to further validate the global potential of SKB264

Kelun-Biotech recorded RMB1.54bn revenue in FY23, primarily from licensing and collaboration agreements with MSD. In Mar 2023, SKB received around RMB1.21bn upfront payment from MSD for out-licensing certain pre-clinical ADC assets, a portion of which was recognized in FY23. Additionally, Kelun-Biotech received RMB215mn milestone payment from MSD related to SKB264 in 4Q23. The Company expects to receive over US\$100mn payments from MSD in FY24. In FY23, Kelun-Biotech spent RMB1.03bn in R&D for its China trials, +21.9% YoY. The net loss shrank to RMB574mn in FY23 from RMB616mn in FY22. As of end-2023, the Company had a sufficient cash balance of RMB2.53bn.

- SKB264 to unlock commercial value upon approval in China in 2H24.** In China, the NDA of SKB264, based on Ph3 trial for 3L+ **TNBC**, has been under review since Dec 2023, with approval expected in 2H24, marking the first approved indication for SKB264. Kelun-Biotech has recently started a Ph3 trial of SKB264 for 1L TNBC treatment (NCT06279364). We anticipate the Ph3 data release of competing TROP2 ADCs in 1L TNBC in 2H24, including Trodelvy's ASCENT-03 study and Dato-DXd's TROPION-Breast02 study. Since SKB264 will also release its Ph2 data in 1L TNBC, we believe the cross trial comparison will help us to better understand SKB264's global potential. For **HR+/HER2-BC**, SKB264's Ph3 trial in 2L+ patients started in Nov 2023. The Company plans to start a pivotal trial of SKB264 +/- A167 in HR+/HER2- BC who progressed endocrine therapy +/- CDK4/6 inhibitor and without additional chemotherapy. Both Dato-DXd and Trodelvy have filed BLA in China for 2L+ HR+/HER2- BC in 1Q24. For **NSCLC**, we expect the Company to file NDA for 3L+ EGFRm NSCLC in 2H24, and to start pivotal trial of SKB264 in 1L EGFRm patients in combo with TKI. Kelun-Biotech plans to start Ph3 trials of SKB264 in 1L EGFR-wt NSCLC in China in 2024, indicating the Company's confidence in this setting.
- MSD expedites the global development process of SKB264.** MSD has vigorously started/registered six global Ph3 trials of SKB264, including four in NSCLC, one in BC and one in endometrial carcinoma. With the potential to be combined with Keytruda to extend its life cycle, SKB264 has become a prominent oncology asset for MSD. We expect MSD to commence additional Ph3 trials of SKB264 in 2024. More importantly, we think the upcoming release of SKB264's Ph2 data in 1L EGFR wild-type NSCLC at ASCO meeting in June will further validate SKB264's potential in this important area.
- Prepare for domestic commercialization.** The Company is assembling a commercial team in anticipation of upcoming approvals for SKB264, A166 (HER2 ADC), A167 (PD-L1), and A140 (cetuximab biosimilar), expected to grow to approximately 500 employees by the end of 2024. We think breast cancer and lung cancer will be the Company's major focuses at the beginning.
- Maintain BUY.** We eagerly await the readout of SKB264 from 1) the Ph2 data in pre-treated NSCLC and the Ph2 data in GC at AACR, 2) the Ph2 data in 1L EGFR wild-type NSCLC at ASCO, 3) the Ph2 data in 1L TNBC at ASCO, and 4) the Ph3 in 3L+ TNBC at ASCO. We revise up our DCF-based TP from HK\$189.25 to HK\$200.77 (WACC: 10.46%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY22A	FY23A	FY24E	FY25E	FY26E
Revenue (RMB mn)	804	1,540	918	1,079	1,638
YoY growth (%)	2,387.3	91.6	(40.4)	17.6	51.7
Net profit (RMB mn)	(616.1)	(574.1)	(658.8)	(786.0)	(726.6)
EPS (Reported) (RMB)	(5.73)	(2.84)	(3.01)	(3.59)	(3.31)
R&D expenses (RMB mn)	(846)	(1,031)	(1,083)	(1,137)	(1,193)
Admin expenses (RMB mn)	(95)	(182)	(218)	(262)	(314)
CAPEX (RMB mn)	(34)	(81)	(200)	(150)	(150)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price **HK\$200.77**

(Previous TP) HK\$189.25)

Up/Downside **25.0%**

Current Price **HK\$160.60**

China Healthcare

Jill WU, CFA

(852) 3900 0842

jillwu@cmbi.com.hk

Andy WANG

(852) 3657 6288

andywang@cmbi.com.hk

Stock Data

Mkt Cap (HK\$ mn)	35,202.8
Avg 3 mths t/o (HK\$ mn)	34.6
52w High/Low (HK\$)	177.90/60.60
Total Issued Shares (mn)	219.2

Source: FactSet

Shareholding Structure

Kelun Pharma	68.5%
MSD	6.1%

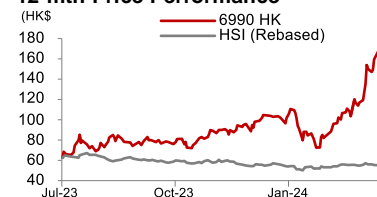
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	49.7%	49.8%
3-mth	54.4%	51.8%
6-mth	110.5%	121.2%

Source: FactSet

12-mth Price Performance



Source: FactSet

Related report:

INITIATION - Kelun-Biotech (6990 HK) - A trailblazer in ADC arena ([link](#)) - 6 Mar 2024

MSD has further expedited global clinical development of SKB264 ([link](#)) - 19 Mar 2024

Figure 1: Clinical trials of SKB264 conducted by MSD

Indication	Trial ID	Stage	Regimen	Primary endpoint	Location	Start date	Primary completion date (est)
Previously treated nsq-NSCLC with EGFR mutations or other genomic alterations (ALK, ROS1, BRAF, NTRK, MET, RET, etc) (pre-treated with TKI, and chemo)	NCT06074588	Ph3	Open label, randomized	Mono vs chemo (docetaxel or pemetrexed)	PFS, OS	US, HK, AU, Israel, etc	Nov 2023 May 2027
1L PD-L1 TPS \geq 50% NSCLC	NCT06170788	Ph3	Open label, randomized	+ Keytruda vs Keytruda mono	OS	US, AU, Turkey	Dec 2023 Jan 2028
post EGFR-TKI nsq-NSCLC (pre-treated with TKI)	NCT06305754	Ph3	Open label, randomized	Mono vs chemo (pemetrexed + carboplatin)	PFS, OS	--	Jun 2024 (est) Sep 2028
Adjuvant NSCLC (Stage II, IIIA, IIIB resectable NSCLC not achieving pCR)	NCT06312137	Ph3	Open label, Non-randomized	SKB264+ Keytruda vs Keytruda	DFS	--	Apr 2024 (est) Feb 2034
Endometrial carcinoma (post chemo and PD(L)-1)	NCT06132958	Ph3	Open label, randomized	Mono vs chemo	PFS, OS	AU, Israel, etc	Dec 2023 Jan 2028
HR+/HER2- BC (post endocrine therapies with one in combo with a CDK4/6 inhibitor)	NCT06312176	Ph3	Open label, randomized	Mono vs +Keytruda vs chemo	PFS	--	Mar 2024 (est) Jul 2027

Source: Clinicaltrial.gov, CMBIGM

Figure 2: Risk-adjusted DCF valuation

DCF Valuation (RMB mn)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(677)	(783)	(699)	75	1,969	3,118	4,371	5,604	6,576	7,336	7,738	7,674
Tax rate	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(677)	(783)	(699)	64	1,674	2,651	3,716	4,763	5,590	6,235	6,577	6,523
+ D&A	40	45	49	56	63	64	66	68	69	71	72	74
- Change in working capital	(208)	(66)	(167)	(279)	(253)	(258)	(199)	(106)	(23)	34	86	82
- Capex	(200)	(150)	(150)	(200)	(200)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
FCFF	(1,046)	(954)	(966)	(359)	1,284	2,357	3,483	4,625	5,536	6,240	6,636	6,579
Terminal value												90,891
FCF + terminal value	(1,046)	(954)	(966)	(359)	1,284	2,357	3,483	4,625	5,536	6,240	6,636	97,469
Present value of enterprise (RMB mn)	39,565											
Net debt (RMB mn)	(482)											
Equity value (RMB mn)	40,046											
No. of shares (mn)	219											
DCF per share (RMB)	182.70											
DCF per share (HK\$)	200.77											
Terminal growth rate	3.0%											
WACC	10.46%											
Cost of equity	14.0%											
Cost of debt	4.5%											
Equity beta	1.1											
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				
	9.46%	9.96%	10.46%	10.96%	11.46%
4.0%	281.29	249.97	223.72	201.44	182.32
3.5%	262.50	234.87	211.42	191.30	173.89
3.0%	246.62	221.93	200.77	182.44	166.45
2.5%	233.02	210.74	191.45	174.63	159.85
2.0%	221.25	200.95	183.24	167.69	153.94

Source: CMBIGM estimates

Figure 4: CMBIGM estimates revision

RMB mn	New			Old			Diff (%)		
	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E
Revenue	918	1,079	1,638	1,039	1,079	1,638	-12%	0%	0%
Gross profit	645	819	1,346	729	819	1,346	-12%	0%	0%
Operating profit	(656)	(772)	(687)	(409)	(610)	(520)	N/A	N/A	N/A
Net profit	(659)	(786)	(727)	(440)	(653)	(586)	N/A	N/A	N/A
EPS (RMB)	(3.01)	(3.59)	(3.31)	(2.01)	(2.98)	(2.67)	N/A	N/A	N/A
Gross margin	70.24%	75.92%	82.17%	70.21%	75.92%	82.17%	+0.03 ppt	0.00 ppt	0.00 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	918	1,079	1,638	1,397	1,781	3,014	-34%	-39%	-46%
Gross profit	645	819	1,346	1,022	1,367	2,380	-37%	-40%	-43%
Operating profit	(656)	(772)	(687)	(505)	(663)	(532)	N/A	N/A	N/A
Net profit	(659)	(786)	(727)	(516)	(680)	(581)	N/A	N/A	N/A
EPS (RMB)	(3.01)	(3.59)	(3.31)	(2.06)	(3.11)	0.59	N/A	N/A	N/A
Gross margin	70.24%	75.92%	82.17%	73.14%	76.77%	78.98%	-2.90 ppt	-0.85 ppt	+3.19 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	918	1,079	1,638
Cost of goods sold	(21)	(277)	(781)	(273)	(260)	(292)
Gross profit	12	527	759	645	819	1,346
Operating expenses	(789)	(946)	(1,143)	(1,301)	(1,591)	(2,033)
Selling expense	0	0	(20)	(41)	(224)	(557)
Admin expense	(96)	(95)	(182)	(218)	(262)	(314)
R&D expense	(728)	(846)	(1,031)	(1,083)	(1,137)	(1,193)
Others	35	(4)	90	41	31	32
Operating profit	(777)	(419)	(383)	(656)	(772)	(687)
Net Interest income/(expense)	(113)	(149)	(84)	(3)	(14)	(40)
Pre-tax profit	(890)	(567)	(468)	(659)	(786)	(727)
Income tax	0	(49)	(106)	0	0	0
After tax profit	(890)	(616)	(574)	(659)	(786)	(727)
Minority interest	0	0	0	0	0	0
Net profit	(890)	(616)	(574)	(659)	(786)	(727)

BALANCE SHEET	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Current assets	298	332	2,807	1,577	1,159	918
Cash & equivalents	82	93	1,529	502	944	550
Restricted cash	37	26	40	40	40	40
Account receivables	79	99	215	7	60	219
Inventories	79	53	63	67	53	48
Financial assets at FVTPL	0	0	634	634	34	34
Other current assets	23	62	327	327	27	27
Non-current assets	515	661	702	862	968	1,068
PP&E	432	530	608	773	883	989
Right-of-use assets	42	117	85	80	75	70
Intangibles	0	3	1	1	1	1
Other non-current assets	40	10	8	8	8	8
Total assets	813	993	3,510	2,439	2,126	1,986
Current liabilities	3,445	4,167	1,110	698	1,171	1,758
Short-term borrowings	2,388	2,891	0	0	500	1,100
Account payables	185	243	523	112	85	71
Other current liabilities	761	787	21	21	21	21
Lease liabilities	2	82	54	54	54	54
Contract liabilities	109	164	511	511	511	511
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	768	1,242	1,828
Share capital	107	107	219	219	219	219
Other reserves	(2,751)	(3,334)	2,110	1,452	666	(61)
Total shareholders equity	(2,644)	(3,226)	2,329	1,671	885	158
Total equity and liabilities	813	993	3,510	2,439	2,126	1,986

CASH FLOW	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	(890)	(567)	(468)	(659)	(786)	(727)
Depreciation & amortization	23	67	32	40	45	49
Tax paid	0	(49)	(106)	0	0	0
Change in working capital	279	35	362	(208)	(66)	(167)
Others	102	195	84	3	14	40
Net cash from operations	(486)	(320)	(97)	(824)	(793)	(804)
Investing						
Capital expenditure	(94)	(34)	(81)	(200)	(150)	(150)
Net proceeds from disposal of short-term investments	0	1	(623)	0	600	0
Others	(1)	1	(321)	0	300	0
Net cash from investing	(94)	(32)	(1,025)	(200)	750	(150)
Financing						
Dividend paid	0	0	0	0	0	0
Net borrowings	155	318	(394)	0	500	600
Proceeds from share issues	534	0	2,853	0	0	0
Others	(42)	(5)	(77)	(3)	(14)	(40)
Net cash from financing	647	313	2,382	(3)	486	560
Net change in cash						
Cash at the beginning of the year	16	82	93	1,529	502	944
Exchange difference	(1)	1	0	0	0	0
Cash at the end of the year	82	44	1,353	502	944	550
GROWTH	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
Revenue	na	2,387.3%	91.6%	(40.4%)	17.6%	51.7%
Gross profit	na	4,368.1%	44.0%	(15.1%)	27.1%	64.2%
PROFITABILITY	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
Gross profit margin	36.5%	65.6%	49.3%	70.2%	75.9%	82.2%
Operating margin	(2,404.6%)	(52.1%)	(24.9%)	(71.5%)	(71.5%)	(42.0%)
Return on equity (ROE)	na	na	na	(32.9%)	(61.5%)	(139.3%)
GEARING/LIQUIDITY/ACTIVITIES	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
Current ratio (x)	0.1	0.1	2.5	2.3	1.0	0.5
VALUATION	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec						
P/B	na	na	6.0	19.4	36.7	205.1

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

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CMB International Global Markets Limited

Address: 45/F, Champion Tower, 3 Garden Road, Hong Kong, Tel: (852) 3900 0888 Fax: (852) 3900 0800

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