

RemeGen (9995 HK)

Wide clinical studies to unlock global potential

In FY22, RemeGen recorded revenue of RMB768mn, including RMB738mn product sales from RC18 and RC48, compared to RMB131mn product sales in FY21. The Company improved its product gross profit margin from 48.9% in 2021 to 63.4% in 2022. The SG&A expenses in FY22 were RMB713mn, +47.7% YoY, due to the significant expansion in salesforce and increasing marketing activities following the approvals of RC18 and RC48 in 1H21. The R&D expenses increased 38.1% YoY to RMB982mn in FY22, mainly driven by the increase in clinical trial spending and employee benefit expenses. In FY22, the Company recorded net loss of RMB999mn compared to net profit of RMB276mn in FY21. Recall that, in FY21, RemeGen received collaboration income of RMB1,291mn for out-licensing RC48 to Seagen. As of end-2022, the Company has a healthy cash balance of RMB2.07bn.

■ **Development of RC18 for multiple autoimmune diseases moved to the next stage.** Conditionally approved for SLE in China, the confirmatory Ph3 trial of RC18 in SLE has released promising efficacy data and the full approval is currently under CDE review. The Company is also exploring RC18 for the treatment of child SLE and lupus nephritis. RemeGen has released positive Ph2 study results for IgA, pSS and MG, all of which are highly underserved patient populations in China. Thus, RemeGen will all start patient enrolment of Ph3 trials for the above-mentioned three indications in 2Q23 in China. In the overseas markets, the MRCT trial of RC18 for SLE is enrolling patients across the US, Europe, APAC and other regions. The Company will start a Ph3 trial of RC18 for MG in the US in 2H23. Additionally, the Ph3 trials of RC18 for IgA and pSS have also been approved by the FDA. With promising PoC data released, we see large potential of RC18 for these underserved autoimmune diseases, and expect potential blockbuster out-license deal.

■ **RC48 to explore frontline treatment and underserved HER2-low market.** The NRDL added RC48 for treatment of 2L UC with stable pricing, which will drive the product sales remarkably. To explore RC48's potential in earlier lines of UC treatment, RemeGen is conducting several studies, including a Ph3 trial of RC48+toripalimab for 1L HER2-expressing UC, a Ph2 trial for perioperative MIBC, and planning to start a trial for NMIBC. For GC, RemeGen received the IND approval to initiate an investigational study assessing RC48 + toripalimab + chemo/trastuzumab for 1L HER2-expressing GC. For BC treatment, a Ph3 trial for HER2-low BC is ongoing with 279 patients enrolled by end-2022. RemeGen also received IND approvals recently to explore RC48 for BC neoadjuvant treatment, including HR+/HER2-low (+Tuoyi/letrozole), HER2+ (+pertuzumab+/-Tuoyi), and HR-/HER2-low (+Tuoyi/chemo). In the US, Seagen plans to start a Ph3 trial of RC48+Keytruda for 1L HER2-expressing UC in 2H23.

■ **Maintain BUY.** We revised our DCF-based TP from HK\$79.13 to HK\$71.89 (WACC: 10.95%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY21A	FY22A	FY23E	FY24E	FY25E
Revenue (RMB mn)	1,424	768	1,282	2,170	3,210
YoY growth (%)	na	(46.1)	67.0	69.3	47.9
Net profit (RMB mn)	276	(999)	(916)	(682)	(305)
EPS (Reported) (RMB)	0.57	(1.88)	(1.68)	(1.25)	(0.56)
R&D expenses (RMB mn)	(711)	(982)	(1,000)	(950)	(900)
Admin expenses (RMB mn)	(220)	(273)	(391)	(553)	(690)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	HK\$71.89
(Previous TP)	HK\$79.13)
Up/Downside	62.3%
Current Price	HK\$44.30

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Stock Data

Mkt Cap (HK\$ mn)	24,110.9
Avg 3 mths t/o (HK\$ mn)	56.9
52w High/Low (HK\$)	70.05/26.00
Total Issued Shares (mn)	544.3

Source: FactSet

Shareholding Structure

HKSCC nominees limited	34.8%
Yantai Rongda	18.8%

Source: HKEx

Share Performance

	Absolute	Relative
1-mth	-13.8%	-16.0%
3-mth	-23.5%	-25.5%
6-mth	16.4%	-1.3%

Source: FactSet

12-mth Price Performance



Source: FactSet

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Figure 1: Risk-adjusted DCF valuation

DCF Valuation (RMB mn)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(907)	(648)	(222)	532	1,398	2,702	3,906	5,412	6,493	7,406	7,493	7,129	7,179
Tax rate	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(907)	(648)	(222)	452	1,188	2,297	3,320	4,600	5,519	6,295	6,369	6,060	6,103
+ D&A	275	303	314	302	291	280	271	262	254	246	239	233	227
- Change in working capital	139	(250)	(295)	(329)	(498)	(493)	(506)	(531)	(349)	(359)	60	280	37
- Capex	(600)	(600)	(400)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
FCFF	(1,093)	(1,195)	(602)	325	881	1,984	2,985	4,231	5,324	6,083	6,569	6,472	6,267
Terminal value													81,214
FCF + Terminal value	(1,093)	(1,195)	(602)	325	881	1,984	2,985	4,231	5,324	6,083	6,569	6,472	87,481
PV of enterprise (RMB mn)	33,555												
Net debt (RMB mn)	(878)												
Equity value (RMB mn)	34,433												
No. of shares (mn)	544												
DCF per shares (RMB)	63.26												
DCF per share (HK\$)	71.89												
Terminal growth rate	3.0%												
WACC	10.95%												
Cost of Equity	14.0%												
Cost of Debt	4.5%												
Equity Beta	1.1												
Risk Free Rate	3.0%												
Market Risk Premium	10.0%												
Target Debt to Asset ratio	30.0%												
Effective Corporate Tax Rate	15.0%												

Source: CMBIGM estimates

Figure 2: Sensitivity analysis (HK\$)

Terminal growth rate	WACC				
	9.95%	10.45%	10.95%	11.45%	11.95%
4.0%	97.36	87.27	78.70	71.35	64.98
3.5%	91.89	82.84	75.07	68.34	62.46
3.0%	87.21	79.00	71.89	65.68	60.23
2.5%	83.16	75.65	69.09	63.33	58.23
2.0%	79.62	72.69	66.60	61.22	56.43

Source: CMBIGM estimates

Figure 3: CMBIGM estimates revision

RMB mn	New			Old			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY22E	FY23E	FY24E
Revenue	1,282	2,170	3,210	1,344	2,189	3,247	-5%	-1%	-1%
Gross profit	984	1,723	2,564	1,031	1,738	2,594	-5%	-1%	-1%
Operating profit	(907)	(648)	(222)	(951)	(762)	(347)	N/A	N/A	N/A
Net profit	(916)	(682)	(305)	(956)	(776)	(382)	N/A	N/A	N/A
EPS (RMB)	(1.68)	(1.25)	(0.56)	(1.76)	(1.43)	(0.70)	N/A	N/A	N/A
Gross margin	76.75%	79.38%	79.89%	76.71%	79.37%	79.88%	+0.03 ppt	+0.01 ppt	+0.01 ppt

Source: Company data, CMBIGM estimates

Figure 4: CMBIGM estimates vs consensus

RMB mn	CMBIGM			Consensus			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY22E	FY23E	FY24E
Revenue	1,282	2,170	3,210	1,597	2,373	3,907	-20%	-9%	-18%
Gross profit	984	1,723	2,564	1,278	1,943	3,149	-23%	-11%	-19%
Operating profit	(907)	(648)	(222)	(736)	(374)	140	N/A	N/A	N/A
Net profit	(916)	(682)	(305)	(685)	(352)	422	N/A	N/A	N/A
EPS (RMB)	(1.7)	(1.3)	(0.6)	(1.3)	(0.6)	0.8	N/A	N/A	N/A
Gross margin	76.75%	79.38%	79.89%	80.01%	81.89%	80.59%	-3.26 ppt	-2.51 ppt	-0.70 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)						
Revenue	0	1,424	768	1,282	2,170	3,210
Cost of goods sold	0	(67)	(270)	(298)	(447)	(645)
Gross profit	0	1,357	498	984	1,723	2,564
Operating expenses	(698)	(1,080)	(1,497)	(1,900)	(2,405)	(2,869)
Selling expense	(24)	(263)	(441)	(667)	(1,020)	(1,348)
Admin expense	(218)	(220)	(273)	(391)	(553)	(690)
R&D expense	(466)	(711)	(982)	(1,000)	(950)	(900)
Others	10	113	199	158	119	69
Operating profit	(669)	282	(992)	(907)	(648)	(222)
Interest income	(29)	(5)	(7)	(8)	(33)	(83)
Pre-tax profit	(698)	276	(999)	(916)	(682)	(305)
Income tax	0	0	0	0	0	0
Minority interest	0	0	0	0	0	0
Net profit	(698)	276	(999)	(916)	(682)	(305)
BALANCE SHEET	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)						
Current assets	2,977	2,300	3,212	1,913	1,988	2,680
Cash & equivalents	2,769	1,757	2,069	925	653	925
Account receivables	0	7	281	241	407	602
Inventories	66	280	523	408	588	813
Financial assets at FVTPL	0	0	0	0	0	0
Other current assets	143	256	339	339	339	339
Non-current assets	1,140	1,859	2,809	3,196	3,556	3,704
PP&E	803	1,578	2,407	2,784	3,133	3,272
Right-of-use assets	138	149	205	215	225	235
Intangibles	5	13	17	17	17	18
Financial assets at FVTPL	13	12	80	80	80	80
Other non-current assets	182	108	100	100	100	100
Total assets	4,118	4,159	6,021	5,109	5,544	6,384
Current liabilities	431	616	892	877	974	1,099
Short-term borrowings	108	0	0	0	0	0
Account payables	63	159	222	206	304	429
Other current liabilities	218	405	610	610	610	610
Lease liabilities	43	52	60	60	60	60
Non-current liabilities	92	96	149	149	1,149	2,149
Long-term borrowings	0	0	0	0	1,000	2,000
Deferred income	44	46	44	44	44	44
Other non-current liabilities	47	51	105	105	105	105
Total liabilities	523	713	1,041	1,025	2,123	3,248
Share capital	490	490	544	544	544	544
Other reserves	3,105	2,957	4,436	3,540	2,877	2,592
Total shareholders equity	3,595	3,446	4,980	4,084	3,421	3,136
Total equity and liabilities	4,118	4,159	6,021	5,109	5,544	6,384

CASH FLOW	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	(698)	276	(999)	(916)	(682)	(305)
Depreciation & amortization	49	65	193	223	251	262
Tax paid	0	0	0	0	0	0
Change in working capital	(117)	(168)	(287)	139	(250)	(295)
Others	105	90	78	79	104	154
Net cash from operations	(660)	264	(1,015)	(474)	(576)	(183)
Investing						
Capital expenditure	(443)	(615)	(800)	(600)	(600)	(400)
Acquisition of subsidiaries/ investments	(102)	0	0	0	0	0
Net proceeds from disposal of short-term investments	102	0	0	0	0	0
Others	(36)	(23)	(62)	(62)	(62)	(62)
Net cash from investing	(479)	(638)	(862)	(662)	(662)	(462)
Financing						
Dividend paid	0	0	0	0	0	0
Net borrowings	(498)	(108)	0	0	1,000	1,000
Proceeds from share issues	4,508	(14)	2,312	0	0	0
Share repurchases	0	(449)	0	0	0	0
Others	(105)	(55)	(7)	(8)	(33)	(83)
Net cash from financing	3,904	(627)	2,306	(8)	967	917
Net change in cash						
Cash at the beginning of the year	35	2,769	1,757	2,069	925	653
Exchange difference	(31)	(10)	0	0	0	0
Cash at the end of the year	2,769	1,757	2,185	925	653	925
GROWTH	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Revenue	na	na	(46.1%)	67.0%	69.3%	47.9%
Gross profit	na	na	(63.3%)	97.7%	75.1%	48.8%
PROFITABILITY	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Gross profit margin	na	95.3%	64.8%	76.7%	79.4%	79.9%
Operating margin	na	19.8%	(129.2%)	(70.8%)	(29.9%)	(6.9%)
Return on equity (ROE)	(41.5%)	7.8%	(23.7%)	(20.2%)	(18.2%)	(9.3%)
GEARING/LIQUIDITY/ACTIVITIES	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Current ratio (x)	6.9	3.7	3.6	2.2	2.0	2.4
VALUATION	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
P/E	na	152.8	na	na	na	na

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

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