InnoCare Pharma (9969 HK)

A successful commercial year for orelabrutinib

InnoCare reported RMB1.04bn revenue in 2021 (vs RMB1.4mn in 2020), including RMB827.0mn upfront payment and collaboration revenue from Biogene and RMB214.7mn net sales of orelabrutinib. R&D expenses increased to RMB721.6mn in 2021 (+79.2% YoY), of which RMB273mn was in-license upfront payment to Incyte for tafasitamab. The net loss in 2021 was RMB66.7mn (vs RMB391.9mn in 2020). InnoCare had a strong cash position of RMB6,550.5mn cash equivalents at the end of 2021.

- **A successful commercial year for orelabrutinib.** After the approval for the treatment of r/r CLL/SLL and r/r MCL in Dec 2020, orelabrutinib generated gross revenue of RMB241.2mn in 2021. Orelabrutinib was included in the NRDL from Jan 2022 with effective annual cost remained largely steady post the NRDL price cut. InnoCare's commercial team has expanded to ~250 employees, and the sales network has penetrated to 260+ cities in China, covering 1,000+ hospitals and 5,000+ doctors. With in-house manufacturing of capacity of 1bn pills being ready in 1H22, we expect the sales of orelabrutinib to further accelerate in 2022.
- **Label expansion of orelabrutinib in progress**. With 500+ patients enrolled in orelabrutinib's trials to date, InnoCare is actively expanding orelabrutinib's labels. The sNDA for r/r WM was accepted by NMPA in 1Q22, and the sNDA filing for r/r MZL is expected in 1H22. Patient enrolment of phase 3 trials of 1L CLL/SLL and 1L MCL is currently ongoing in China. In the US, a registrational phase 2 trial for r/r MCL may complete patient enrollment this year. In the autoimmune disease space, InnoCare and Biogen are conducting a global phase 2 trial for MS patients in the US, Europe and China. The Company has completed a phase 2 trial for SLE in 2021 which showed promising efficacy results. Orelabrutinib has the potential to become the first BTK inhibitor to treat SLE, with oral administration advantages over other SLE therapies.
- **Major catalysts of pipeline assets**. Tafasitamab is the only approved anti-CD19 antibody for r/r DLBCL in the US and Europe. The Company expects to issue the first prescription of tafasitamab in Hainan province in 1H22 and to file the NDA for tafasitamab in HK and Macau this year. The IND application of a bridging study has been accepted by NMPA. ICP-192 (pan-FGFR) is being evaluated in phase 1/2 trials for solid tumors in China and the US. InnoCare expects to initiate iCCA registrational trials and to release PoC data for head & neck cancer in 2022.
- **Maintain BUY**. InnoCare has built a robust pipeline that includes 1 commercial product (2 approved indications and 6 additional registrational trials), 10 clinical stage assets, and 4-5 IND enabling stage candidates. We expect orelabrutinib to continue its strong sales growth momentum in 2022 and beyond. We revised down our TP from HK$24.66 to HK$19.24 (WACC: 10.26%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec) (RMB mn)	FY20A	FY21A	FY22E	FY23E	FY24E
Revenue	1	1,043	820	845	1,965
Attributable net profit (loss)	(391)	(65)	(429)	(330)	304
R&D expense	(403)	(722)	(800)	(700)	(600)
ROA (%)	(9)	(1)	(6)	(5)	4
Consensus EPS (RMB)	N/A	N/A	(0.34)	(0.04)	N/A
Net gearing (%)	Net cash	Net cash	Net cash	Net cash	Net cash
Current ratio (x)	39	19	48	44	25

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	**HK$19.24**
(Pervious TP	HK$24.66)
Up/Downside	**+63.35%**
Current Price	**HK$11.78**

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Mkt. Cap. (HK$ mn)	17,666
Avg. 3mths t/o (HK$ mn)	29.67
52W High/Low (HK$)	32.05/8.86
Total Issued Shares (mn)	1,500

Source: Bloomberg

Shareholding Structure

Hillhouse Capital	13.30%
Pang Kee Chan	10.79%
Vivo Capital	8.20%
Renbin Zhao	7.99%
Jisong Cui	7.02%
GIC	6.51%
Other investors	46.19%

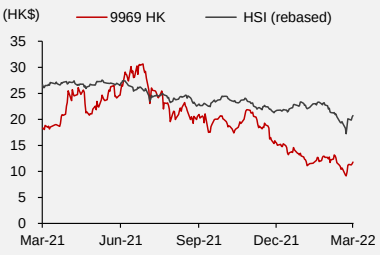
Source: Bloomberg

Share performance

	Absolute	Relative
1-mth	-7.4%	-0.5%
3-mth	-26.4%	-22.3%
6-mth	-44.0%	-38.1%

Source: Bloomberg

12-mth price performance



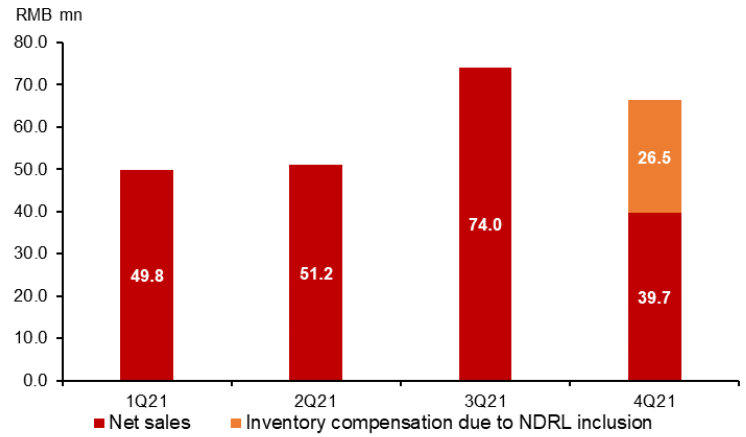
Source: Bloomberg

Auditor: Ernst & Young
Web-site: www.innocarepharma.com

Related report:

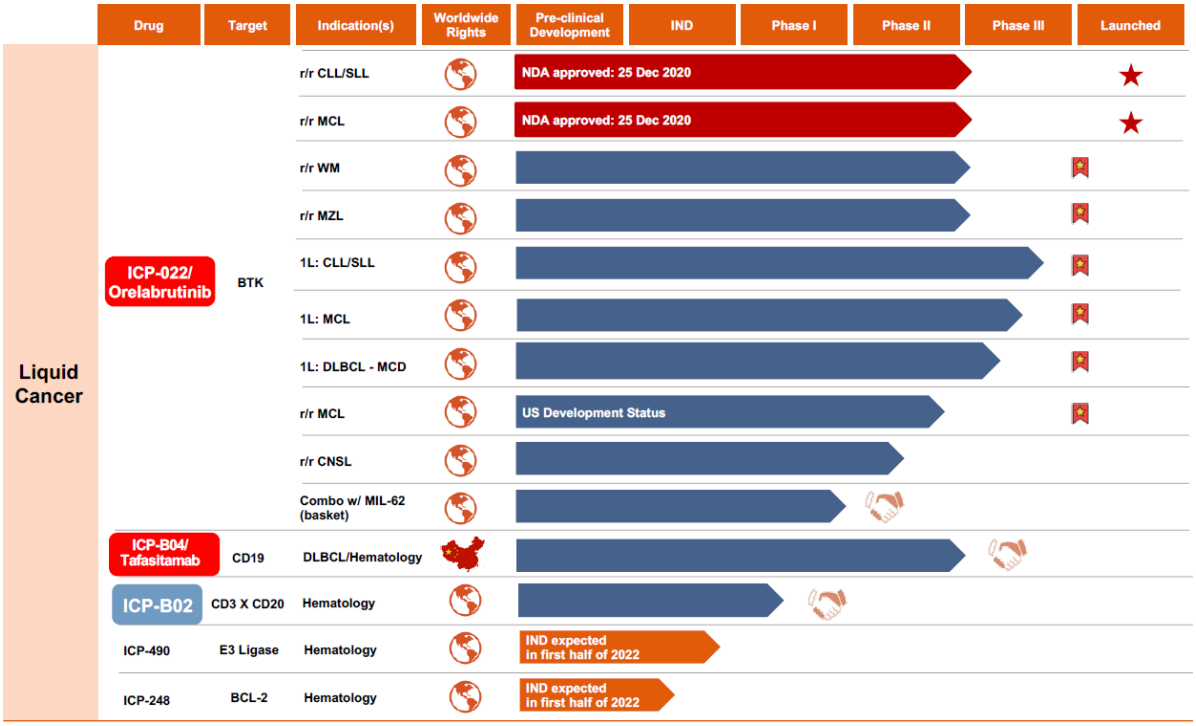
1. Fruitful out/in licensing deals – 30 Aug 2021
2. Orelabrutinib showed impressive efficacy in r/r-CLL/SLL – 20 Apr 2021
3. Entering into commercial stage – 29 Mar 2021

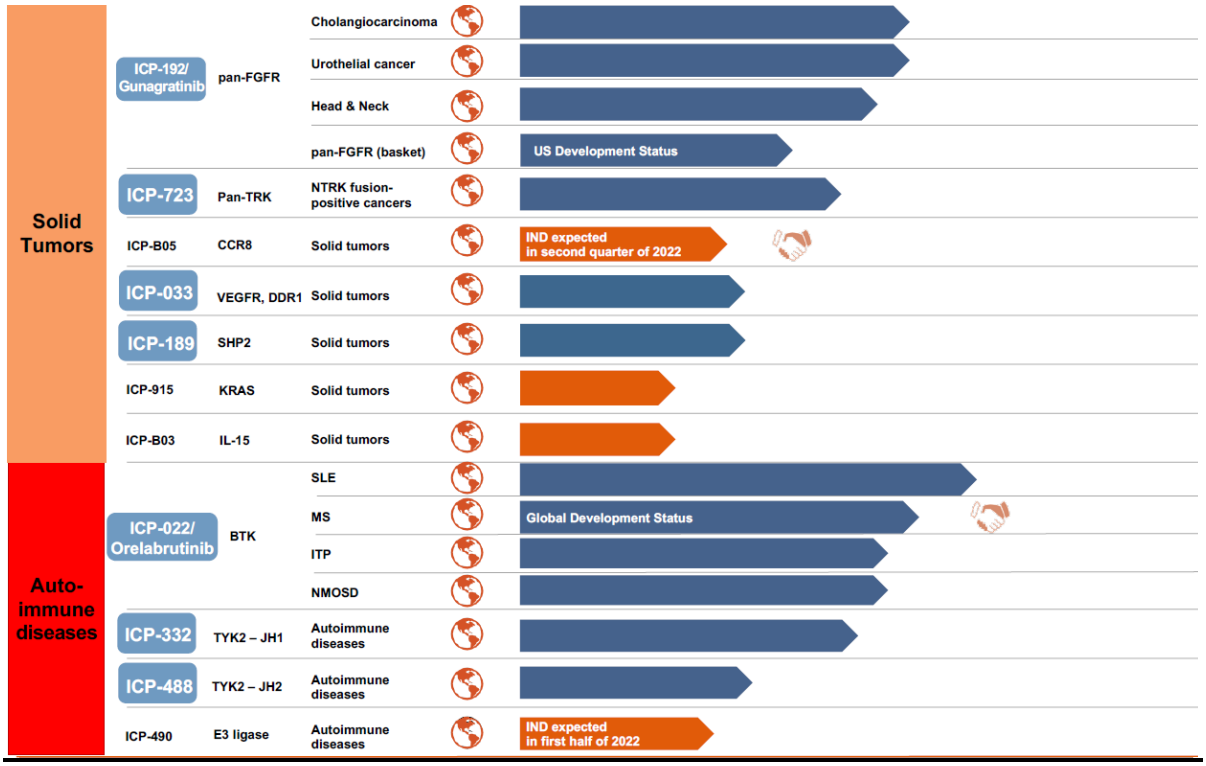
Figure 1: Quarterly sales of orelabrutinib in 2021



Source: Company data, STAR listing prospectus, CMBIGM

Figure 2: Pipelines of InnoCare (as of Mar 2022)





Source: Company data, CMBIGM

Figure 3: Cross trial compassion of BTK inhibitors in r/r CLL/SLL

	orelabrutinib	zanubrutinib		acalabrutinib	
Trial ID	NCT03493217	NCT03734016 (BeiGene's head-to-head trial to compare zanubrutinib to ibrutinib)		NCT02477696 (AZ's head-to-head trial to compare acalabrutinib to ibrutinib)	
Trial phase	Phase 2	Phase 3		Phase 3	
Indication	r/r CLL/SLL	r/r CLL/SLL		r/r CLL/SLL	
Study design	150 mg oral daily administration of orelabrutinib	Randomized 1:1 to receive zanubrutinib 160 mg BID or ibrutinib 420 mg QD		Randomized 1:1 to receive acalabrutinib 100 mg BID or ibrutinib 420 mg QD	
Subject number	80	415		533	
Trial location	China	Multiple regions (US, China, Europe etc.)		Multiple regions (US, Europe etc.)	
Follow-up time	33.1 months	15 months		40.9 months	
Primary endpoint	ORR	ORR (CR+PR)		PFS	
Efficacy	**orelabrutinib**	**zanubrutinib**	**ibrutinib**	**acalabrutinib**	**ibrutinib**
ORR (CR+PR+PR-L)	93.80%	88.40%	81.30%		
CR/CRi	26.30%	1.90%	1.40%		
nPR (nodular PR)		0.50%	0.00%		
PR	56.30%	75.80%	61.10%		
PR-L (PR with lymphocytosis)	11.30%	10.10%	18.80%		
DOR	Median DOR not reached; 30-month DOR 67.2%				
PFS	Median PFS not reached; 30-month PFS 69.7%	12 month PFS rate 94.9%	12 month PFS rate 84.0%	38.4 months	38.4 months
OS		12 month OS rate 97.0%	12 month OS rate 92.7%	Median OS not reached	Median OS not reached
Safety					
Atrial fibrillation/flutter	No case of atrial fibrillation nor secondary malignancy was reported, no patient had ≥3 grade hypertension and only one patient had ≥3 grade diarrhea. Major hemorrhage was reported in 2 patients. 2 patients (2.5%) and 5 patients (6.3%) reported treatment related AEs leading to treatment discontinuation or dose reduction, respectively.	2.50%	10.10%	9.40%	16.00%
Cardiac disorders of any grade		13.70%	25.10%	24.10%	30.00%
Cardiac disorders (Gr≥3)		2.50%	6.80%	8.60%	9.50%
Hypertension (Gr≥3)		10.80%	10.60%	4.10%	9.10%
Infections (Gr≥3)		12.70%	17.90%	30.80%	30.00%

Source: Company data, CMBIGM

Figure 4: Cross trial compassion of BTK inhibitors in r/r WM

	orelabrutinib	zanubrutinib		acalabrutinib
Trial ID	NCT04440059	NCT03053440 (BeiGene's head-to-head trial to compare zanubrutinib to ibrutinib)		NCT02180724
Trial phase	Phase 2	Phase 3		Phase 2
Indication	r/r WM	r/r WM		r/r WM
Study design	Single arm	Randomized 1:1 to receive zanubrutinib or ibrutinib		Single arm
Subject number	47	164		92
Trial location	China	Multiple regions (US, China, Europe etc.)		Multiple regions (US, Europe, etc)
Follow-up time	10.5 months	19.4 months		27.4 months
Primary endpoint	Major response rate (CR, VGPR and PR)	CR and VGPR rate		ORR
	orelabrutinib	**zanubrutinib**	**ibrutinib**	**acalabrutinib**
MRR	78.7%	78.0%	80.0%	
CR	0.0%	0.0%	0.0%	
VGPR	14.9%	29.0%	20.0%	
PR	63.8%	49.0%	61.0%	
MR	8.5%	16.0%	14.0%	
ORR	87.2%	94.0%	94.0%	93.0%
SD	10.6%	4.0%	3.0%	
DCR	97.9%	98.0%	97.0%	
Safety	The most common AEs included thrombocytopenia (all grades, 27.7 %), hemorrhage (27.7 %), infections (21.3 %), and neutropenia (19.1 %), which were mostly mild to moderate. No treatment-emergent grade ≥ 3 events were reported for diarrhea, atrial fibrillation/flutter, hypertension, and hemorrhage. Treatment-related AEs prompted dose reduction and study drug discontinuation in 6.4% and 2.1%, espectively.	Grade ≥3 AEs were reported in 63% and 58% of ibrutinib and zanubrutinib patients, respectively. Grade ≥3 hypertension and pneumonia were reported at a ≥5% higher incidence among ibrutinib patients vs zanubrutinib patients; grade ≥3 neutropenia was reported at a ≥5% higher incidence among zanubrutinib patients. 41% and 40% of ibrutinib and zanubrutinib patients, respectively, experienced ≥1 serious AE. The most common serious AEs (ibrutinib vs zanubrutinib) were pneumonia (9 patients vs 1), neutropenia and febrile neutropenia (each 0 vs 3), influenza (1 vs 3), and pyrexia and sepsis (each 3 vs 2).		Grade 3–4 adverse events occurring in ≥ 5% of patients were neutropenia (16%) and pneumonia (7%). Grade 3–4 atrial fibrillation occurred in 1% patient and grade 3–4 bleeding occurred in 3% patients. The most common serious adverse events were lower respiratory tract infection (7%), pneumonia (7%), pyrexia (4%), cellulitis (n=3%), fall (3%), and sepsis (3%). Pneumonia (5%) and lower respiratory tract infection (4%) were considered treatment related. One treatment-related death was reported (intracranial hematoma).

Source: Company data, CMBIGM

Figure 5: Cross trial compassion of BTK inhibitors in r/r MCL

	orelabrutinib	zanubrutinib		ibrutinib	acalabrutinib
Trial ID	NCT03494179	NCT03206970	NCT02343120	Pooled analysis of NCT01646021, NCT01599949, NCT01236391	NCT02213926
Trial phase	Phase 1/2	Phase 2	Phase 1/2	Phase 2 & 3	Phase 2
Indication	r/r MCL	r/r MCL	r/r MCL	r/r MCL	r/r MCL
Subject number	106	86	32	370	124
Follow-up time	16.4 months	35.3 months	18.8 months	41.4 months	38.1 months
Primary endpoint	ORR (CR, PR and VGPR)	ORR	ORR	PFS, ORR	ORR
ORR	87.90%	83.70%	84.00%	69.70%	81.00%
CR	34.30%	77.90%	25.00%	27.00%	48.00%
PR	53.60%	5.80%	59.00%	42.70%	34.00%
SD	6.00%			11.60%	8.00%
DCR	93.90%			81.30%	90.00%
DOR	Median DOR not reached	Median DOR not reached	Median DOR 18.5 months	Median DOR 21.8 months	Median DOR 28.6 months; 36-month DOR rate 41.9%
PFS	Median PFS not reached	Median PFS 33 months; 30 month PFS-free rate 57.3%	Median PFS 21.1 months	Median PFS 12.5 months	Median PFS 22.0 months; 36-month PFS rate 37.2%
OS		Median OS not reached		Median OS 26.7 months	Median OS 59.2 months
Safety	Grade ≥ 3 treatment-related AEs were reported in 33% of patients; The most common AEs included thrombocytopenia, neutropenia, leukopenia, and hypertension.	Gr ≥3 TEAEs (≥5%) were decreased neutrophil count (18.6%), pneumonia (12.8%), platelet count decreased, white blood cell count decreased (7.0% each), and anemia (5.8%). Four new pts had gr ≥3 infections (18.6%), and no new pt had gr ≥3 hypertension (3.5% total) or major hemorrhage. No cases of atrial fibrillation/flutter, gr ≥3 cardiac AEs, second primary malignancies, or tumor lysis syndrome were reported. No new TEAEs led to death (8.1% total), treatment discontinuation (9.3% total), or dose reduction (2.3% total).	Of the 118 patients (together the trial NCT03206970), 13.6% of patients discontinued treatment due to adverse events in the trials, with the most frequent being pneumonia (3.4%). Adverse events leading to dose reduction occurred in 3.4% of patients.	Treatment discontinuation rates due to disease progression, AEs, and death were 59.2%, 10.3%, and 5.1%, respectively.	Selected AEs included atrial fibrillation (any-grade, 2.4%; grade 3/4, 0%), hypertension (any-grade, 4.0%; grade 3/4, 1.6%), hemorrhage (any-grade, 37.1%; grade 3/4, 4.0%), and infections (any-grade, 67.7%; grade 3/4, 16.9%). 10.5% of patients experienced dose reductions, with 2.4% doing so because of toxicities. A total of 15 patients (12.1%) experienced treatment-emergent AEs that resulted in treatment discontinuation.

Source: Company data, CMBIGM

Figure 6: Risk-adjusted DCF valuation

DCF Valuation (in RMB mn)	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(538)	(427)	264	767	1,666	2,007	2,494	2,920	3,406
Tax rate	0%	0%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(538)	(427)	225	652	1,416	1,706	2,120	2,482	2,895
+ D&A	5	5	5	5	5	5	5	5	5
- Change in working capital	(197)	(2)	(107)	(95)	(142)	(58)	(76)	(74)	(82)
- Capex	(200)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
FCFF	**(930)**	**(524)**	**22**	**462**	**1,179**	**1,553**	**1,949**	**2,313**	**2,718**
Terminal value									**38,546**
FCF + Terminal value	(930)	(524)	22	462	1,179	1,553	1,949	2,313	41,264

Present value of enterprise (RMB mn)	19,811
Net Debt	-3,905
Minorities	52
Equity value (RMB mn)	23,664
Corporate value (HK$ mn)	**28,858**
# of shares outstanding	1,499,673,235
TP per share (HK$)	**19.24**
Terminal growth rate	**3.00%**
WACC	**10.26%**
Cost of Equity	12.84%
Cost of Debt	5.00%
Equity Beta	0.82
Risk Free Rate	3.00%
Market Risk Premium	12.00%
Target Debt to Asset ratio	30.00%
Effective Corporate Tax Rate	15.00%

Source: CMBIGM estimates

Figure 7: Sensitivity analysis (HK$)

		WACC				
		9.26%	**9.76%**	**10.26%**	**10.76%**	**11.26%**
	4.00%	26.17	23.61	21.47	19.66	18.10
	3.50%	24.38	22.15	20.27	18.66	17.27
Terminal growth rate	**3.00%**	22.87	20.92	**19.24**	17.80	16.54
	2.50%	21.59	19.85	18.35	17.04	15.89
	2.00%	20.48	18.92	17.56	16.36	15.31

Source: CMBIGM estimates

Figure 8: CMBIGM estimates revision

	New			Old			Diff (%)		
RMB mn	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E
Revenue	820	845	1,965	685	707	1,666	20%	20%	18%
Gross Profit	722	744	1,730	562	587	1,399	29%	27%	24%
Operating Profit	(427)	(329)	359	(77)	8	579	N/A	N/A	-38%
Net profit	(431)	(332)	302	(78)	5	491	N/A	N/A	-38%
EPS (RMB)	(0.29)	(0.22)	0.20	(0.05)	0.00	0.33	N/A	N/A	-38%
Gross Margin	88.00%	88.00%	88.00%	82.00%	83.00%	84.00%	+6.00 ppt	+5.00 ppt	+4.00 ppt

Source: Company data, CMBIGM estimates

Figure 9: CMBIGM estimates vs consensus

	CMBIGM			Consensus			Diff (%)		
RMB mn	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E
Revenue	820	845	1,965	535	1,546	N/A	53%	-45%	N/A
Gross Profit	722	744	1,730	441	1,314	N/A	64%	-43%	N/A
Operating Profit	(427)	(329)	359	(428)	322	N/A	N/A	N/A	N/A
Net profit	(431)	(332)	302	(419)	60	N/A	N/A	N/A	N/A
EPS (RMB)	(0.29)	(0.22)	0.20	(0.34)	0.04	N/A	N/A	N/A	N/A
Gross Margin	88.00%	88.00%	88.00%	82.48%	84.98%	N/A	+5.52 ppt	+3.02 ppt	N/A

Source: Company data, CMBIGM estimates

Financial Statements

Income statement

YE 31 Dec (RMB mn)	FY20A	FY21A	FY22E	FY23E	FY24E
Revenue	**1**	**1,043**	**820**	**845**	**1,965**
Orelabrutinib - risk adjusted	0	215	485	845	1,353
ICP-192 - risk adjusted	0	0	0	0	277
ICP-105 - risk adjusted	0	0	0	0	0
Others	1	828	335	0	335
Cost of sales	0	(66)	(98)	(101)	(236)
Gross profit	**1**	**977**	**722**	**744**	**1,730**
Other income	271	218	130	118	114
Selling & distribution expenses	(68)	(298)	(315)	(338)	(571)
R&D expenses	(403)	(722)	(800)	(700)	(600)
Administrative expenses	(89)	(140)	(164)	(152)	(314)
Other expenses	(34)	(52)	0	0	0
Operating profit (loss)	**(322)**	**(17)**	**(427)**	**(329)**	**359**
Fair value changes of convertible redeemable preferred shares	(69)	0	0	0	0
Finance costs	(1)	(3)	(4)	(4)	(4)
Pre-tax profit (loss)	**(392)**	**(19)**	**(431)**	**(332)**	**355**
Income tax	0	(47)	0	0	(53)
Minority interests	0	2	2	2	2
Attributable net profit (loss)	**(391)**	**(65)**	**(429)**	**(330)**	**304**

Cash flow summary

YE 31 Dec (RMB mn)	FY20A	FY21E	FY22E	FY23E	FY24E
Profit before tax	**(464)**	**(20)**	**(431)**	**(332)**	**355**
Depreciation and	11	5	5	5	5
Change in working capital	(57)	156	(197)	(2)	(107)
Others	337	(133)	(107)	(94)	(144)
Net income tax paid	0	(47)	0	0	(53)
Net operating cash flow	**(173)**	**7**	**(730)**	**(424)**	**108**
Interest received	33	135	110	98	94
Purchases of PP&E	(251)	(387)	(200)	(100)	(100)
Purchases of other intangible	(0)	0	0	0	0
Net purchases of financial	82	0	0	0	0
Others	(971)	(348)	0	0	0
Net investing cash flow	**(1,107)**	**(600)**	**(90)**	**(2)**	**(6)**
Net proceeds from shares	2,253	2,555	0	0	0
Bank borrowing, net	(9)	0	0	0	0
Acquisition of non-controlling interests	0	0	0	0	0
Others	(6)	(3)	(4)	(4)	(4)
Net financing cash flow	**2,238**	**2,552**	**(4)**	**(4)**	**(4)**
FX changes	(252)	0	0	0	0
Net change in cash	959	1,960	(823)	(430)	99
Cash at the beginning	1,594	3,970	5,929	5,105	4,675
Cash at the end	**2,301**	**5,929**	**5,105**	**4,675**	**4,774**

Balance sheet

YE 31 Dec (RMB mn)	FY20A	FY21E	FY21A	FY23E	FY24E
Non-current assets	**445**	**980**	**1,176**	**1,271**	**1,367**
PP&E	306	430	628	726	824
Goodwill	3	3	3	3	3
Other intangible assets	37	34	34	33	33
Right-of-use assets	97	136	134	132	130
Investment in JVs	1	21	21	21	21
Other non-current assets	1	356	356	356	356
Current assets	**4,092**	**6,417**	**5,577**	**5,151**	**5,461**
Inventories	2	10	16	17	39
Trade receivables	0	45	45	46	108
Prepayments, other receivables & other	121	116	93	96	223
Cash and cash equivalents	3,970	5,929	5,105	4,675	4,774
Others	0	317	317	317	317
Current liabilities	**104**	**329**	**115**	**118**	**221**
Trade payables	6	85	49	50	116
Loans and borrowings	0	0	0	0	0
Other payables and accruals	85	205	27	28	65
Lease liabilities	7	20	20	20	20
Loans from a related party	0	0	0	0	0
Others	7	19	19	19	19
Non-current liabilities	**1,273**	**1,409**	**1,409**	**1,409**	**1,409**
Convertible redeemable preferred	0	0	0	0	0
Convertible loan	1,150	1,201	1,201	1,201	1,201
Loans and borrowings	0	0	0	0	0
Others	123	209	209	209	209
Total net assets	**3,161**	**5,659**	**5,228**	**4,895**	**5,197**
Minority interest	56	54	52	50	48
Shareholders' equity	**3,104**	**5,605**	**5,176**	**4,845**	**5,149**

Key ratios

YE 31 Dec	FY20A	FY21A	FY22E	FY23E	FY24E
Sales mix (%)					
Orelabrutinib - risk adjusted	0	21	59	100	69
ICP-192 - risk adjusted	0	0	0	0	14
ICP-105 - risk adjusted	0	0	0	0	0
Others	100	79	41	1	18
Total	100	100	100	101	101
Profit & loss ratios (%)					
Gross margin	100	94	88	88	88
EBITDA margin	NA	NA	NA	NA	14
Pre-tax margin	NA	NA	NA	NA	18
Net margin	NA	NA	NA	NA	15
Effective tax rate	0	-231	0	0	15
Balance sheet ratios					
Current ratio (x)	39	19	48	44	25
Trade receivables turnover	8	20	20	20	20
Trade payables turnover	250	180	180	180	180
Net debt to total equity ratio (%)	Net	Net	Net	Net	Net
Returns (%)					
ROE	NA	NA	NA	NA	NA
ROA	(9)	(1)	(6)	(5)	4

Source: Company data, CMBIGM estimates

Disclosures & Disclaimers

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