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Ascentage Pharma (6855 HK) Encouraging results of APG-2575 and APG-115 released at 2021 ASCO Annual Meeting

- Four studies were selected for presentations at 2021 ASCO meeting, including two oral presentations. The presented studies were 1) a global phase 1 study of the Bcl-2 inhibitor APG-2575 in r/r CLL and other hematologic malignancies (#7502, oral presentation), 2) a global phase II study of APG-115 (MDM2-p53 inhibitor) in combination with pembrolizumab for melanoma or advanced solid tumors that have failed immuno-oncologic drugs (#2506, oral presentation), 3) a phase 1/2 study of APG-115 with or without platinum chemotherapy, in p53 wild-type salivary gland carcinoma (TPS6094), and 4) a phase 1b/2 study of APG-1252 plus paclitaxel for r/r SCLC (TPS8589).
- First-in-human study of APG-2575 delivered promising preliminary PoC data. As the second Bcl-2 inhibitor entering clinical development globally, APG-2575 has demonstrated favorable safety and efficacy in the global phase 1 study. As of 15 Apr 2021, 36 patients have been treated with APG-2575 as a single agent at doses ranging from 20 mg to 1,200 mg, including 15 patients with r/r CLL/SLL and the remaining patients with other hematologic malignancies. 12 out of the 15 r/r CLL/SLL patients achieved PR (ORR=80%). More importantly, all of the 15 r/r CLL/SLL patients were previously treated by CD20, and 27% of them had previously received BTK inhibitors. APG-2575 demonstrated superior safety given no DLT was observed at the maximum dose of 1,200 mg. The MTD has not been reached, and no laboratory or clinical TLS has been reported. 600mg daily has been selected as the RP2D based on the clinical results. We expect APG-2575 to enter pivotal phase 2 stage by end-2021 or early-2022. The drug has best-in-class potential given its shorter daily ramp-up schedule (vs weekly for venetoclax) and limited TLS.
- Encouraging preliminary efficacy of APG-115 plus pembrolizumab for IO resistant melanoma. APG-115 is orally bioavailable MDM2-p53 antagonist. As of 15 Apr 2021, 102 PD-1/PD-L1 inhibitor-resistant patients had been treated with APG-115 of 150mg Q2D (RP2D) in combination with pembrolizumab. Among the 29 evaluable melanoma patients, there were 1 CR, 6 PR and 9 SD patients, indicating 24.1% ORR (7/29) and 55.2% DCR (16/29). Besides melanoma, PR cases were also found in patients with MPNST, liposarcoma, NSCLC and UC. The combination therapy also showed promising efficacy in MPNST and liposarcoma which pembrolizumab has no approved indications.
- Maintain BUY. We forecast HQP-1351 to obtain NMPA's approval by 4Q21E. We believe APG-2575 could become a global best-in-class Bcl-2 inhibitor. We lifted DCF-based TP from HK\$62.04 to HK\$66.04 to reflect higher probability of success of APG-2575 (WACC: 11.72%, terminal growth of 2.0%).

Earnings Summary

(YE 31 Dec)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue (RMB mn)	15	12	12	269	3,170
YoY growth (%)	113	(14)	0	2,061	1,078
Net profit (RMB mn)	(1,481)	(678)	(857)	(943)	85
EPS (RMB)	(12.69)	(3.14)	(3.39)	(3.73)	0.34
Consensus EPS (RMB)	N/A	N/A	(3.26)	(2.52)	(0.87)
R&D expenses (RMB mn)	(464)	(565)	(700)	(800)	(951)
Capex (RMB mn)	(77)	(252)	(450)	(200)	(200)
Current ratio	4.5	3.9	3.3	2.2	4.2

Source: Company data, Bloomberg, CMBIS estimates



BUY (Maintain)

Target Price (Previous TP Up/Downside Current Price HK\$66.04 HK\$62.04) +50.96% HK\$43.75

China Healthcare Sector

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Stock Data

Mkt. Cap. (HK\$ mn)	11,063
Avg. 3mths t/o (HK\$ mn)	81.64
52W High/Low (HK\$)	54.7/ 24.6
Total Issued Shares (mn)	253
Source: Bloomberg	

Shareholding Structure

Management	32.17%
Collected Mind (3SBio)	4.85%
Sino Biopharma	2.2%
Institution investors	26.28%
Free float	34.5%
Source: SZSE	

Share Performance

	Absolute	Relative
1-mth	12.0%	11.4%
3-mth	38.0%	36.9%
6-mth	47.8%	35.1%
Source: Bloomberg	1	

Source: Bloomberg

12-mth Price Performance



Source: Bloomberg

Auditor: Ernst & Young

Related reports

- Gear up for commercialization 7 Apr 2021
- 2. Promising progress on HQP-1351 and APG-2575 - 16 Dec 2020

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Figure 1: Earnings revision

New			Old			Diff (%)			
RMB mn	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E
Revenue	12	269	3,170	12	269	2,990	0%	0%	6%
Gross Profit	12	188	2,536	12	188	2,392	0%	0%	6%
Operating Profit	(835)	(906)	169	(835)	(906)	160	N/A	N/A	6%
Net profit	(857)	(943)	85	(857)	(943)	77	N/A	N/A	10%
EPS (RMB)	(3.39)	(3.73)	0.34	(3.39)	(3.73)	0.31	N/A	N/A	10%
Gross Margin	100.00%	70.00%	80.00%	100.00%	70.00%	80.00%	0.00ppt	0.00ppt	0.00ppt

Source: Company data, CMBIS estimates

Figure 2: CMBIS estimates vs consensus

<u> </u>	CMBIS				Consensus			Diff (%)		
RMB mn	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E	FY21E	FY22E	FY23E	
Revenue	12	269	3,170	38	529	1,811	-67%	-49%	75%	
Gross Profit	12	188	2,536	34	432	1,545	-64%	-56%	64%	
Operating Profit	(835)	(906)	169	(904)	(638)	160	N/A	N/A	5.61%	
Net profit	(857)	(943)	85	(907)	(736)	(220)	N/A	N/A	N/A	
EPS (RMB)	(3.39)	(3.73)	0.34	(3.26)	(2.52)	(0.87)	N/A	N/A	N/A	
Gross Margin	100.00%	70.00%	80.00%	91.00%	81.68%	85.33%	+9.00ppt	-11.68ppt	-5.33ppt	

Source: Company data, Bloomberg, CMBIS estimates

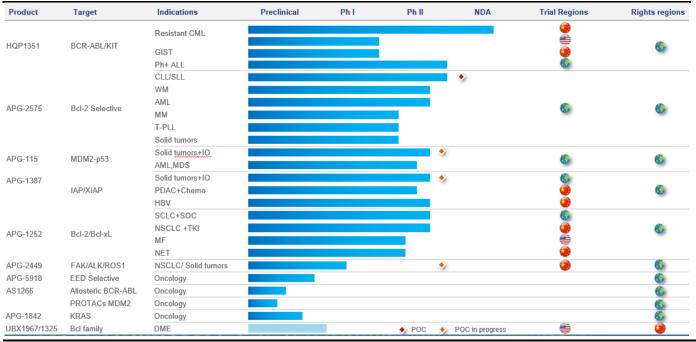
Figure 3: Base case valuation on risk-adjusted DCF valuation

DCF Valuation (in Rmb mn)		2021E	2022E	2023E	2024E	2025E	2026E	2027E
EBIT		(857)	(943)	100	1,343	2,228	2,906	3,540
Tax rate		0%	0%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)		(857)	(943)	85	1,142	1,893	2,470	3,009
+ D&A		58	98	110	120	129	137	144
 Change in working capital 		29	(97)	(1,101)	(1,018)	(531)	(453)	(457)
- Capex		(450)	(200)	(200)	(200)	(200)	(200)	(200)
FCFF		(1,220)	(1,142)	(1,107)	43	1,291	1,954	2,496
Terminal value								26,204
FCF + Terminal value		(1,220)	(1,142)	(1,107)	43	1,291	1,954	28,700
Discount factor		1.0	0.9	0.8	0.7	0.6	0.6	0.5
PV of FCF		(1,220)	(1,023)	(887)	31	829	1,123	14,764
Present value of enterprise (RMB mn)	13,618							
Net debt (RMB mn)	(244)							
Equity value (RMB mn)	13,862							
Equity value (HK\$ mn)	16,701							
No. of shares outstanding	252,875,62							
÷	3							
DCF per share (HK\$)	66.04							
Terminal growth rate	2.0%							
WACC	11.72%							
Cost of Equity	14.6%							
Cost of Debt	6.0%							
Equity Beta	1.1							
Risk Free Rate	3.0%							
Market Risk Premium	10.5%							
Target Debt to Asset ratio	30.0%							
Effective Corporate Tax Rate	15.0%							

Source: CMBIS estimates



Figure 4: Key pipelines of Ascentage



Source: Company data, CMBIS

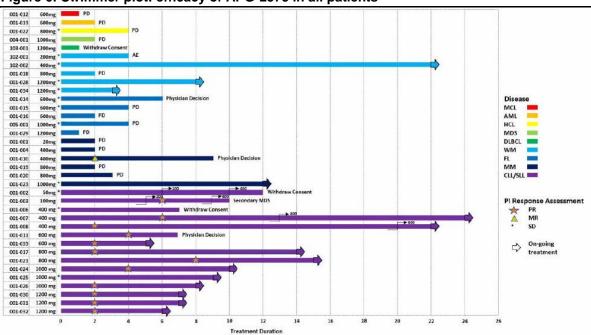
Figure 5: Global clinical-stage Bcl-2 inhibitor candidates

Drug candidate	Target	Progress	Target indication	Company
APG-1252	BcI-2/BcI-xL	Phase Ib/II	SCLC, Lymphoma	Ascentage
APG-2575	Bcl-2	Phase Ib/II	Blood cancer	Ascentage
Navitoclax / ABT-263	Bcl-2/Bcl-xL	Phase II	MF, Ovarian cancer	Abbvie
Navitoclax / ABT-263	Bcl-2/Bcl-xL	Phase I/II	SCLC	Abbvie
Navitoclax / ABT-263	Bcl-2/Bcl-xL	Phase I	ALL, etc.	Abbvie
Venetoclax / ABT-199	Bcl-2	Marketed	CLL, AML, MM, MCL, etc.	Abbvie
BCI-201 (S-55746)	Bcl-2	Phase I	MCL, FL, AML, MDS	Novartis
BGB-11417	Bcl-2	Phase I	Mature B-Cell malignancies	Beigene

Source: F&S, CMBIS



Figure 6: Swimmer plot: efficacy of APG-2575 in all patients



Source: ASCO 2021 Annual Meeting, CMBIS

Figure 7: Baseline characteristics of patients with CLL/SLL

	Overall (N = 15)		Overall (N = 15)
Diagnosis, no. (%)		Prognostic features, no. (%)	
CLL	14 (93.3)	Del(17p)/TP53 mutation	2 (13.3)
SLL	1 (6.7)	Del(11q)	1 (6.7)
		CD38+	3 (20.0)
Rai stage at enrollment, no. (%)		Unmutated IgVH	9 (60.0)
1-11	8 (53.3)		
III-IV	7 (46.7)	Previous therapy, no. (%)	
		Any previous fludarabine therapy	2 (13.3)
IPI, no. (%)		Previous CD20 antibody-based therapy	15 (100.0)
Low	3 (20.0)	Previous BTKi therapy	4 (26.7)
Intermediate	5 (33.3)		
High	6 (40.0)	Bulky nodes, no. (%)	
Very high	1 (6.7)	> 5 cm	4 (26.7)

BTKi, Bruton tyrosine kinase inhibitor; IPI, International Prognostic Index. ^aData cutoff: April 15, 2021.

Source: ASCO 2021 Annual Meeting, CMBIS

Financial Summary

Income statement

YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Revenue	15	12	12	269	3,170
License fee income	11	10	10	10	10
Provision of R&D services	4	3	3	3	3
Cost of sales	(2)	(2)	0	(81)	(634)
Gross profit	12	10	12	188	2,536
Other income	49	45	30	30	30
Selling & distribution expenses	0	(1)	(10)	(135)	(951)
Milestone payment	0	0	(20)	(20)	(20)
Administrative expenses	(162)	(129)	(148)	(171)	(475)
R&D expenses	(464)	(565)	(700)	(800)	(951)
Operating profit	(564)	(639)	(835)	(906)	169
Other expenses	(914)	(30)	0	0	0
Finance costs, net	(4)	(6)	(21)	(37)	(69)
Pre-tax profit	(1,482)	(675)	(857)	(943)	100
Income tax	2	(2)	0	0	(15)
Minority interests	0	0	0	0	0
Net profit (Net loss)	(1,481)	(678)	(857)	(943)	85

Cash flow summary

YE 31 Dec (RMB mn)	FY19A	FY20A	FY21E	FY22E	FY23E
Profit before tax	(1,482)	(675)	(857)	(943)	100
Depreciation & amortization, etc.	26	27	58	98	110
Change in working capital	15	52	29	(97)	(1,101)
Tax paid	0	(2)	0	0	(15)
Others	980	(80)	21	37	69
Net cash from operating	(460)	(678)	(748)	(905)	(838)
Capex	(77)	(252)	(450)	(200)	(200)
(Purchases of)/proceeds from retrieval of other financial assets, net	20	0	0	0	0
Other investing activities	(143)	144	0	0	0
Net cash from investing	(201)	(107)	(450)	(200)	(200)
Net proceeds from shares issued	432	623	969	0	0
Bank borrowing	50	433	0	800	800
Capital repurchase	0	0	0	0	0
Interests paid	(4)	(6)	(21)	(37)	(69)
Net cash from financing	442	1,040	948	763	731
FX changes	1	(113)	0	0	0
Net change in cash	(219)	255	(251)	(342)	(307)
Cash at the beginning of the year	957	882	1,024	774	431
Cash at the end of the year	739	1,024	774	431	125

Balance sheet Key ratios YE 31 Dec (RMB mn) FY19A FY20A FY21E FY22E FY23E Non-current assets 1,093 1,184 PP&E 1,061 Right-of-use assets Other intangible assets Goodwill Equity investment measured at Other non-current assets Current assets 1,079 1,482 Inventories Trade receivables Prepayments, other receivables Other financial assets Cash and bank balances 1,024 **Current liabilities** Bank loans Trade payables Other payables and accruals Contract liabilities Non-current liabilities 1,408 2,208 1,279 2,079 Bank loans Deferred tax liabilities Convertible redeemable preferred Other non-current liabilities Others Total net assets **Minority interest** Shareholders' equity

YE 31 Dec	FY19A	FY20A	FY21E	FY22E	FY23E
	FTI9A	FT2UA	FIZIE	FIZZE	FT23E
Sales mix (%)	70				
License fee income	73	79	79	4	0
Provision of R&D services	27	21	21	1	0
Total	100	100	100	5	0
Profit & loss ratios (%)					
Gross margin	86	84	100	70	80
EBITDA margin	N/A	N/A	N/A	N/A	N/A
Pre-tax margin	N/A	N/A	N/A	N/A	N/A
Net margin	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0	(0)	15	15	15
Balance sheet ratios					
Current ratio (x)	4	4	3	2	4
	A N/A	N/A	N/A	N/A	N/A
Trade receivables turnover days					
Trade payables turnover days	N/A	N/A	N/A	N/A	N/A
Net debt to total equity ratio (%)	N/A	N/A	N/A	N/A	N/A
Total debt to asset ratio (%)	26	51	47	99	96
Returns (%)					
ROE	N/A	N/A	N/A	(2)	1
ROA	N/A	N/A	N/A	(1)	0
Per share data					
	(40.00)	(0.4.4)	(0,00)	(0,70)	0.04
EPS (RMB)	(12.69)	(3.14)	(3.39)	(3.73)	0.34
DPS (RMB)	0.00	0.00	0.00	0.00	0.00
BVPS (RMB)	0.00	3.92	3.79	0.06	0.40

Source: Company data, CMBIS estimates



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