

Ascentage Pharma (6855 HK)

HQP-1351 obtained ODD from US FDA

Ascentage announced that the US FDA has granted HQP-1351 an Orphan Drug Designation (ODD) for the treatment of chronic myeloid leukemia (CML). This implies promising commercial opportunities for HQP-1351 in the US market. Besides, HQP-1351 is conducting a pivotal phase II study for drug-resistant CML in China. Ascentage plans to submit an NDA to the NMPA for HQP-1351 within this year. Maintain BUY with our DCF-based TP unchanged at HK\$45.8.

- HQP-1351 obtained ODD from US FDA.** As a third generation BCR-ABL inhibitor targeting drug-resistant CML, HQP-1351 showed comparable efficacy to and improved safety profile than ponatinib in phase I study. In Jul 2019, the US FDA approved HQP-1351 to initiate a phase Ib trial. The ODD for HQP-1351 indicates the unmet medical need for r/r-CML patients with acquired resistance to current TKI treatments (imatinib, dasatinib and nilotinib). Receiving an ODD qualifies HQP-1351 various development incentives, including a tax credit of 50% in clinical trials, a waiver of the NDA fee, R&D grant, and, most importantly, seven years of US market exclusivity upon approval. In China, HQP1351 has finished patient enrollment of its pivotal phase II trial for r/r CML in Sep 2019 and plans to submit an NDA for treatment of r/r CML with T315I mutation to the NMPA in 2020E.
- APG-2575 to initiate four phase Ib/II trials in the US and China.** APG-2575 recently received approvals from the US FDA for entering a Phase Ib/II trial for r/r CLL/SLL (first patient enrolled in Mar 2020), a Phase Ib/II trial for WM; and approval from the NMPA for a Phase Ib trial for r/r AML and Phase Ib/II trial for r/r CLL/SLL. Previously, Phase I study of APG-2575 commenced in the US, Australia and China has shown a favorable safety profile with no DLTs (dose limiting toxicities), no TLS (tumor lysis syndrome) and the MTD (maximum tolerable dose) not reached at 20-600mg dose levels; and promising anticancer activity.
- Strong in-house R&D capability in apoptosis pathways and next generation TKIs.** Ascentage has a pipeline of eight clinical stage small molecule candidates, conducting 30+ phase I or II clinical trials in China, US and Australia. The most advanced drug, HQP1351, is granted ODD in the US and expected to receive NDA approval in China by 2021E. APG-2575 has entered into Phase Ib/II trials while APG-1252, APG-115 and APG-1387 are in Phase I trials.
- Maintain BUY with TP not changed.** We forecast drug sales to start in 2022E and apply risk-adjusted revenue to those drugs with different probability of success (PoS). We maintain our price target of HK\$45.8 based on an 8-year DCF valuation (WACC: 10.98%, terminal growth 3.0%).

Earnings Summary

(YE 31 Dec)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue (RMB mn)	7	15	7	7	91
YoY growth (%)	8	113	(52)	0	1,199
Net profit (RMB mn)	(345)	(1,481)	(729)	(794)	(835)
EPS (RMB)	N/A	(12.69)	(3.49)	(3.80)	(3.99)
Consensus EPS (RMB)	N/A	N/A	(3.54)	(3.59)	(3.93)
R&D expenses (RMB mn)	(250)	(464)	(600)	(600)	(600)
Capex (RMB mn)	(48)	(77)	(400)	(450)	(100)
Current ratio	9.4	4.5	0.5	0.1	0.1

Source: Company data, Bloomberg, CMBIS estimates

BUY (Maintain)

Target Price **HK\$45.8**
 (Previous TP **HK\$45.8**)
Up/Downside **+45.4%**
Current Price **HK\$31.5**

China Healthcare Sector

Sam HU, PhD

(852) 3900 0882
samhu@cmbi.com.hk

Jill WU, CFA

(852) 3900 0842
jillwu@cmbi.com.hk

Amy GE

(852) 3761 8778
amyge@cmbi.com.hk

Stock Data

Mkt. Cap. (HK\$ mn)	6,580
Avg. 3mths t/o (HK\$ mn)	2.68
52W High/Low (HK\$)	53.6/19.8
Total Issued Shares (mn)	209

Source: Bloomberg

Shareholding Structure

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

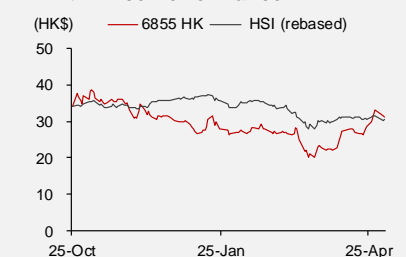
Source: SZSE

Share Performance

	Absolute	Relative
1-mth	42.2%	38.4%
3-mth	16.7%	30.9%
6-mth	-17.8%	-4.6%

Source: Bloomberg

12-mth Price Performance



Source: Bloomberg

Auditor: Ernst & Young

Related reports

- Pipeline in smooth progress; First NDA filing this year – 31 Mar 2020
- Encouraging progress in innovative BCL-2 inhibitor – 11 Mar 2020
- Pioneer in developing apoptosis pathway drug – 20 Dec 2019

Figure 1: Key pipeline of Ascentage

Candidate	Mechanism	Lead Indications	Preclinical	Ph I	Ph II	Countries
HQP1351	BCR-ABL mutant	Resistant CML	[Progress bar: Preclinical to Ph II]			pivotal phase II China
	KIT	GIST	[Progress bar: Preclinical to Ph I]			China
APG-2575	Bcl-2 Selective	CLL/SLL	[Progress bar: Preclinical to Ph II]			China, U.S. & Australia
		WM	[Progress bar: Preclinical to Ph II]			U.S. & Australia
APG-1252	Bcl-2/Bcl-xL	AML	[Progress bar: Preclinical to Ph II]			China
		SCLC/NSCLC	[Progress bar: Preclinical to Ph II]			China, U.S. & Australia
APG-115	MDM2-p53	NSCLC (Combo)	[Progress bar: Preclinical to Ph II]			China
		Solid tumors(IO combo)	[Progress bar: Preclinical to Ph II]			China & U.S.
APG-1387	IAP Dimer	AML	[Progress bar: Preclinical to Ph I]			China & U.S.
		Solid tumors(IO combo)	[Progress bar: Preclinical to Ph II]			China & U.S.
AT-101	Bcl-2/Bcl-xL/Mcl-1	CLL	[Progress bar: Preclinical to Ph II]			China & U.S.
APG-2449	FAK/ALK/ROS1	NSCLC	[Progress bar: Preclinical to Ph I]			China
HQP8361	c-Met selective	Cancer (c-Met+)	[Progress bar: Preclinical to Ph I]			China
Bcl-2 related Strategic relationship with Unity to develop senolytic drugs.						U.S.

Source: Company data, CMBIS

Figure 2: CMBIS estimates vs consensus

(RMB mn)	CMBIS		Consensus		Diff (%)	
	FY20E	FY21E	FY20E	FY21E	FY20E	FY21E
Revenue	7	7	11	41	-35%	-83%
Gross profit	7	7	11	39	-35%	-82%
Operating profit	(713)	(747)	(732)	(791)	N/A	N/A
Net profit	(729)	(794)	(774)	(863)	N/A	N/A
EPS (RMB)	(3.49)	(3.80)	(3.54)	(3.59)	N/A	N/A

Source: Company data, CMBIS estimates

Figure 3: Peers comparison

Ticker	Company	TP (HKD)	Rating	Current Px (HKD)	Mkt Cap (USD mn)	Px Change (%)			AVG Trading Turnover (HKD mn)			IPO Date	IPO Px (HKD)
						30 d	60 d	90 d	30 d	60 d	90 d		
6855.HK	Ascentage	45.8	BUY	31.5	849	42%	18%	17%	4	3	3	2019-10-28	34.20
2696.HK	Henlius	57.2	BUY	43.6	3,057	18%	5%	17%	3	2	2	2019-09-25	49.60
6160.HK	Beigene	N/A	NR	84.1	10,924	5%	-9%	-13%	12	11	10	2018-08-08	108.00
1801.HK	Innovent	N/A	NR	35.9	6,218	13%	3%	14%	148	172	177	2018-10-31	13.98
1877.HK	Junshi	N/A	NR	40.0	4,878	19%	39%	68%	39	28	20	2018-12-24	19.38
6185.HK	CanSino	N/A	NR	155.4	4,464	9%	78%	111%	326	263	195	2019-03-28	22.00
9969.HK	InnoCare	N/A	NR	13.9	2,312	9%	N/A	N/A	99	160	160	2020-03-23	8.95
9966.HK	AlphaMab	N/A	NR	17.1	2,039	21%	-4%	22%	19	14	15	2019-12-12	10.20
2616.HK	CStone	N/A	NR	7.4	982	-10%	-31%	-35%	11	7	6	2019-02-26	12.00

Source: Bloomberg, CMBIS

Financial Summary

Income statement

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue	7	15	7	7	91
License fee income	0	11	0	0	0
Provision of R&D services	7	4	7	7	7
Cost of sales	0	(2)	0	0	(27)
Gross profit	7	12	7	7	64
Other income	61	49	19	19	19
Selling & distribution expenses	0	0	0	0	(45)
Milestone payment	0	0	0	(20)	(20)
Administrative expenses	(90)	(162)	(139)	(153)	(168)
R&D expenses	(250)	(464)	(600)	(600)	(600)
Operating profit	(272)	(564)	(713)	(747)	(751)
Other expenses	(38)	(914)	0	0	0
Finance costs, net	(37)	(4)	(16)	(48)	(84)
Pre-tax profit	(347)	(1,482)	(729)	(794)	(835)
Income tax	2	2	0	0	0
Minority interests	0	0	0	0	0
Net profit (Net loss)	(345)	(1,481)	(729)	(794)	(835)

Cash flow summary

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Profit before tax	(347)	(1,482)	(729)	(794)	(835)
Depreciation & amortization, etc.	18	26	24	63	102
Change in working capital	27	15	(13)	0	(18)
Tax paid	0	0	0	0	0
Others	64	980	16	48	84
Net cash from operating	(238)	(460)	(702)	(684)	(666)
Capex	(48)	(77)	(400)	(450)	(100)
(Purchases of)/proceeds from retrieval of other financial assets, net	376	20	0	0	0
Other investing activities	(35)	(143)	0	0	0
Net cash from investing	293	(201)	(400)	(450)	(100)
Net proceeds from shares issued	911	432	0	0	0
Bank borrowing	35	50	600	1,000	800
Capital repurchase	(76)	0	0	0	0
Interests paid	(2)	(4)	(16)	(48)	(84)
Net cash from financing	860	442	584	952	716
FX changes	27	1	0	0	0
Net change in cash	915	(219)	(517)	(182)	(50)
Cash at the beginning of the year	15	957	882	365	183
Cash at the end of the year	957	739	365	183	133

Balance sheet

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Non-current assets	239	296	672	1,059	1,057
PP&E	27	94	484	886	897
Right-of-use assets	40	49	40	31	22
Other intangible assets	75	72	66	61	56
Goodwill	25	25	25	25	25
Equity investment measured at FVTPL	60	32	32	32	32
Other non-current assets	12	25	25	25	25
Current assets	990	909	392	210	182
Inventories	0	0	0	0	7
Trade receivables	0	0	0	0	15
Prepayments, other receivables	19	27	27	27	27
Other financial assets	14	0	0	0	0
Cash and bank balances	957	882	365	183	133
Current liabilities	105	202	789	1,789	2,593
Bank loans	38	92	692	1,692	2,492
Trade payables	5	13	0	0	4
Other payables and accruals	63	97	97	97	97
Contract liabilities	0	0	0	0	0
Non-current liabilities	2,136	113	113	113	113
Bank loans	4	9	9	9	9
Deferred tax liabilities	19	17	17	17	17
Convertible redeemable preferred shares	2,076	0	0	0	0
Other non-current liabilities	0	0	0	0	0
Others	37	86	86	86	86
Total net assets	(1,012)	890	162	(633)	(1,467)
Minority interest	0	0	0	0	0
Shareholders' equity	(1,012)	890	162	(633)	(1,467)

Source: Company data, CMBIS estimates

Key ratios

YE 31 Dec	FY18A	FY19A	FY20E	FY21E	FY22E
Sales mix (%)					
License fee income	1	73	0	0	0
Provision of R&D services	99	27	100	100	8
Total	100	100	100	100	8
Profit & loss ratios (%)					
Gross margin	100	86	100	100	70
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	0	0	0
Balance sheet ratios					
Current ratio (x)	9	4	0	0	0
Trade receivables turnover	N/A	N/A	N/A	N/A	N/A
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 (%)	182	26	85	150	218
Returns (%)					
ROE	N/A	N/A	N/A	N/A	1
ROA	N/A	N/A	N/A	N/A	(1)
Per share data					
EPS (RMB)	N/A	(12.69)	(3.49)	(3.80)	(3.99)
DPS (RMB)	0.00	0.00	0.00	0.00	0.00
BVPS (RMB)	N/A	Net	1.61	7.27	11.34

Disclosures & Disclaimers

Analyst Certification

The research analyst who is primary responsible for the content of this research report, in whole or in part, certifies that with respect to the securities or issuer that the analyst covered in this report: (1) all of the views expressed accurately reflect his or her personal views about the subject securities or issuer; and (2) no part of his or her compensation was, is, or will be, directly or indirectly, related to the specific views expressed by that analyst in this report.

Besides, the analyst confirms that neither the analyst nor his/her associates (as defined in the code of conduct issued by The Hong Kong Securities and Futures Commission) (1) have dealt in or traded in the stock(s) covered in this research report within 30 calendar days prior to the date of issue of this report; (2) will deal in or trade in the stock(s) covered in this research report 3 business days after the date of issue of this report; (3) serve as an officer of any of the Hong Kong listed companies covered in this report; and (4) have any financial interests in the Hong Kong listed companies covered in this report.

Disclaimer

CMBIS or its affiliate(s) have investment banking relationship with the issuers covered in this report in preceding 12 months.

CMBIS Ratings

BUY	: Stock with potential return of over 15% over next 12 months
HOLD	: Stock with potential return of +15% to -10% over next 12 months
SELL	: Stock with potential loss of over 10% over next 12 months
NOT RATED	: Stock is not rated by CMBIS
OUTPERFORM	: Industry expected to outperform the relevant broad market benchmark over next 12 months
MARKET-PERFORM	: Industry expected to perform in-line with the relevant broad market benchmark over next 12 months
UNDERPERFORM	: Industry expected to underperform the relevant broad market benchmark over next 12 months

CMB International Securities Limited

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

CMB International Securities Limited ("CMBIS") is a wholly owned subsidiary of CMB International Capital Corporation Limited (a wholly owned subsidiary of China Merchants Bank)

Important Disclosures

There are risks involved in transacting in any securities. The information contained in this report may not be suitable for the purposes of all investors. CMBIS does not provide individually tailored investment advice. This report has been prepared without regard to the individual investment objectives, financial position or special requirements. Past performance has no indication of future performance, and actual events may differ materially from that which is contained in the report. The value of, and returns from, any investments are uncertain and are not guaranteed and may fluctuate as a result of their dependence on the performance of underlying assets or other variable market factors. CMBIS recommends that investors should independently evaluate particular investments and strategies, and encourages investors to consult with a professional financial advisor in order to make their own investment decisions.

This report or any information contained herein, have been prepared by the CMBIS, solely for the purpose of supplying information to the clients of CMBIS and/or its affiliate(s) to whom it is distributed. This report is not and should not be construed as an offer or solicitation to buy or sell any security or any interest in securities or enter into any transaction. Neither CMBIS nor any of its affiliates, shareholders, agents, consultants, directors, officers or employees shall be liable for any loss, damage or expense whatsoever, whether direct or consequential, incurred in relying on the information contained in this report. Anyone making use of the information contained in this report does so entirely at their own risk.

The information and contents contained in this report are based on the analyses and interpretations of information believed to be publicly available and reliable. CMBIS has exerted every effort in its capacity to ensure, but not to guarantee, their accuracy, completeness, timeliness or correctness. CMBIS provides the information, advices and forecasts on an "AS IS" basis. The information and contents are subject to change without notice. CMBIS may issue other publications having information and/ or conclusions different from this report. These publications reflect different assumption, point-of-view and analytical methods when compiling. CMBIS may make investment decisions or take proprietary positions that are inconsistent with the recommendations or views in this report.

CMBIS may have a position, make markets or act as principal or engage in transactions in securities of companies referred to in this report for itself and/or on behalf of its clients from time to time. Investors should assume that CMBIS does or seeks to have investment banking or other business relationships with the companies in this report. As a result, recipients should be aware that CMBIS may have a conflict of interest that could affect the objectivity of this report and CMBIS will not assume any responsibility in respect thereof. This report is for the use of intended recipients only and this publication, may not be reproduced, reprinted, sold, redistributed or published in whole or in part for any purpose without prior written consent of CMBIS.

Additional information on recommended securities is available upon request.

For recipients of this document in the United Kingdom

This report has been provided only to persons (I) falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended from time to time) ("The Order") or (II) are persons falling within Article 49(2) (a) to (d) ("High Net Worth Companies, Unincorporated Associations, etc.") of the Order, and may not be provided to any other person without the prior written consent of CMBIS.

For recipients of this document in the United States

This report is intended for distribution in the United States to "major US institutional investors", as defined in Rule 15a-6 under the US, Securities Exchange Act of 1934, and may not be furnished to any other person in the United States. Each major US, institutional investor that receives a copy of this research report by its acceptance hereof represents and agrees that it shall not distribute or provide this research report to any other person.

For recipients of this document in Singapore

This report is distributed in Singapore by CMBI (Singapore) Pte. Limited (CMBISG) (Company Regn. No. 201731928D), an Exempt Financial Adviser as defined in the Financial Advisers Act (Cap. 110) of Singapore and regulated by the Monetary Authority of Singapore. CMBISG may distribute reports produced by its respective foreign entities, affiliates or other foreign research houses pursuant to an arrangement under Regulation 32C of the Financial Advisers Regulations. Where the report is distributed in Singapore to a person who is not an Accredited Investor, Expert Investor or an Institutional Investor, as defined in the Securities and Futures Act (Cap. 289) of Singapore, CMBISG accepts legal responsibility for the contents of the report to such persons only to the extent required by law. Singapore recipients should contact CMBISG at +65 6350 4400 for matters arising from, or in connection with the report.