Ascentage Pharma (6855 HK)

Collaboration with AstraZeneca for development of APG-2575

On 22 Jun 2020, Ascentage announced it has entered a clinical collaboration with AstraZeneca (AZN US, NR) to carry out a global multicenter clinical trial to evaluate the combination of APG-2575 with CALQUENCE® (acalabrutinib, a BTK inhibitor) for r/r CLL/SLL. We lifted TP to HK$70.7 and maintain BUY.

- **APG-2575 collaboration with AstraZeneca's acalabrutinib for r/r CLL/SLL.** Ascentage announced a clinical collaboration with Acerta Pharma, the hematology research and development center of excellence of AstraZeneca, in a clinical trial evaluating the combination of APG-2575 (Bcl2 inhibitor) and acalabrutinib (BTK inhibitor) for r/r CLL/SLL. This trial is a global, multicenter, open-label Phase Ib/II dose-escalation and dose-expansion study to assess the safety and anticancer activity of APG-2575 with or without acalabrutinib. The study was already initiated in the US with the dosing of first patient, and planned to expand in Europe, and Australia.
- **The excellent results of venetoclax + ibrutinib combination implies promising outlook of Bcl-2+BTK combination**. In ASCO 2018, a Phase II trial (CAPTIVATE, NCT02910583) showed excellent results of venetoclax +ibrutinib in 1L CLL/SLL with 100% ORR and 77% of MRD(-) response in peripheral blood after six cycles. Results were updated in ASH 2019 with undetectable MRD rates of 75% and 72% in the peripheral blood and bone marrow, respectively. As the second Bcl-2 inhibitor entered into clinical stage globally, APG-2575 + acalabrutinib also has large potential, in our view.
- **APG-2575 has good preliminary data and multiple trials ongoing**. APG-2575 is under four phase Ib/II trials in the US and China, including a Phase Ib/II trial for r/r CLL/SLL (first patient enrolled in Mar 2020) in US, a Phase Ib/II trial for WM in US; a Phase Ib trial for r/r AML in China and a Phase Ib/II trial for r/r CLL/SLL in China. Phase I study of APG-2575 has shown a promising efficacy in enrolled patients, of which six out of eight CLL patients achieved hematological CR. In addition, no DLTs (dose limiting toxicities) and no TLS (tumor lysis syndrome) was observed with the MTD (maximum tolerable dose) not reached at 20-800mg dose levels so far.
- **Lift TP to HK$70.7 and maintain BUY.** We raised APG-2575's PoS (probability of success) for risk-adjusted revenue starting to generate from 2023E to reflect the positive impact of this collaboration. Given that the clinical cooperation with AstraZeneca indicates faster clinical execution and higher chances of success for APG-2575, we lifted TP to HK$70.7 based on an 8-year DCF valuation (WACC: 10.98%, terminal growth of 3.0%).

Earnings Summary

(YE 31 Dec)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue (RMB mn)	7	15	7	7	152
YoY growth (%)	8	113	(52)	0	2,073
Net profit (RMB mn)	(345)	(1,481)	(729)	(794)	(822)
EPS (RMB)	N/A	(12.69)	(3.49)	(3.80)	(3.94)
Consensus EPS (RMB)	N/A	N/A	(3.54)	(3.42)	(2.18)
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

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BUY (Maintain)

Target Price	**HK$70.7**
(Previous TP	HK$61.1)
Up/Downside	**+63.1%**
Current Price	**HK$46.4**

China Healthcare Sector

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Stock Data

Mkt. Cap. (HK$ mn)	9,056
Avg. 3mths t/o (HK$ mn)	16.74
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%

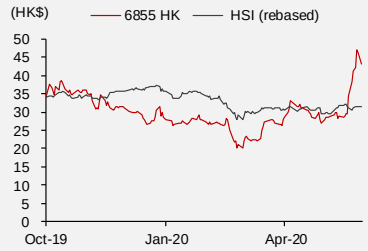
Source: SZSE

Share Performance

	Absolute	Relative
1-mth	64.9%	62.5%
3-mth	120.7%	104.2%
6-mth	47.6%	66.9%

Source: Bloomberg

12-mth Price Performance



Source: Bloomberg

Auditor: Ernst & Young

Related reports
HQP-1351 NDA submitted in China – 19 Jun 2020

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https://euromoney.com/brokers

Figure 1: Revenue forecast of APG-2575 and key assumptions

	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
APG-2575 sales in CLL/SLL (RMB mn)	1,197	1,892	2,554	2,993	3,959	4,474	5,019	5,594
Probability of success for CLL/SLL	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
APG-2575 sales in AML (RMB mn)	196	327	448	532	657	719	784	836
Probability of success for AML	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*	*30%*
APG-2575 sales in MM (RMB mn)	172	337	506	620	781	856	933	1,006
Probability of success for MM	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
Risk-adjusted APG-2575 sales (RMB mn)	**683**	**1,095**	**1,487**	**1,749**	**2,294**	**2,581**	**2,885**	**3,199**

Source: Company data, CMBIS

Figure 2: CMBIS estimates vs consensus

(RMB mn)	CMBIS			Consensus			Diff (%)		
	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E
Revenue	7	7	152	11	133	416	-35%	-95%	-63%
Gross profit	7	7	106	10	126	353	-33%	-94%	-70%
Operating profit	(713)	(747)	(739)	(732)	(791)	(732)	N/A	N/A	(732)
Net profit	(729)	(794)	(822)	(774)	(698)	(527)	N/A	N/A	(774)
EPS (RMB)	(3.49)	(3.80)	(3.94)	(3.54)	(3.42)	(2.18)	N/A	N/A	(3.54)

Source: Company data, CMBIS estimates

Figure 3: Peers comparison

Company	Ticker	TP (HKD)	Rating	Current Px (HKD)	Mkt Cap (USD mn)	Px Change (%)			AVG Trading Turnover (HKD mn)			IPO	IPO Px
						30 d	60 d	90 d	30 d	60 d	90 d	Date	(HKD)
Ascentage	**6855.HK**	**61.1**	**BUY**	**46.35**	**1,249**	**72%**	**66%**	**111%**	**41**	**24**	**17**	**2019-10-28**	**34.20**
InnoCare	9969 HK	16.2	BUY	52.15	3,657	23%	20%	60%	7	5	4	2019-09-25	49.60
Henlius	2696.HK	57.2	BUY	14.34	2,385	3%	-4%	48%	41	62	102	2020-03-23	8.95
Beigene	6160.HK	N/A	NR	111.30	14,514	17%	16%	39%	21	19	16	2018-08-08	108.00
Innovent	1801.HK	N/A	NR	49.50	8,577	22%	42%	72%	168	172	160	2018-10-31	13.98
Junshi	1877.HK	N/A	NR	54.00	5,681	31%	59%	96%	59	62	49	2018-12-24	19.38
CanSino	6185.HK	N/A	NR	185.30	5,323	-17%	30%	59%	441	403	371	2019-03-28	22.00
AkesoBio	9926.HK	N/A	NR	31.90	3,239	24%	N/A	N/A	135	N/A	N/A	2020-04-24	16.18
AlphaMab	9966.HK	N/A	NR	17.40	2,096	-7%	-3%	24%	67	49	37	2019-12-12	10.20
CStone	2616.HK	N/A	NR	9.76	1,295	35%	8%	16%	20	18	14	2019-02-26	12.00
Kintor	9939.HK	N/A	NR	15.54	741	N/A	N/A	N/A	N/A	N/A	N/A	2020-05-22	20.15

Source: Bloomberg, CMBIS

Figure 4: Summary of Venetoclax (Bcl-2 inhibitor) trials

	Venetoclax	Venetoclax+Rituxan vs Bendamustine+Rituximab	Venetoclax+Azacitidine or decitabine	Venetoclax+low-dose cytarabine	Venetoclax+Gazvya vs. Chlorambucil+Gazvya	Venetoclax+Ibrutinib
Source	FDA approved (Apr 2016)	FDA approved (Jun 2018)	FDA approved (Nov 2018)	FDA approved (Nov 2018)	FDA approved (May 2019)	ASCO 2018; ASH 2019
Trial ID	M13-982 (NCT01889186)	MURANO (NCT02005471)	M14-358 (NCT02203773)	M14-387 (NCT02287233)	CLL14 (NCT02242942)	CAPTIVATE (NCT02910583)
Indication	r/r CLL/SLL with 17p Del	r/r CLL/SLL	AML	AML	1L CLL/SLL	1L CLL/SLL
Enrolment (N)	106	389	115	82	432	164
Phase	Phase II	Phase III	Phase Ib	Phase I/II	Phase II	Phase II
Regimen	20mg QD, increasing over a 5-week period to 400mg	VEN+R: 5-week ramp up of venetoclax to 400mg, then 6 cycles of VEN+R, followed by VEN-mono for up to 2 years Vs B+R: 70 mg/m^2+ 375 mg/m^2 for 6 cycles	VEN: 5-week ramp up of venetoclax to 400mg QD Azacitidine: 75 mg/m^2 day1-7 per cycle Decitabine: 20 mg/m^2 day1-7 per cycle	VEN: 5-week ramp up of venetoclax to 600mg QD Cytarabine: 20 mg/m^2 day1-10 per cycle	VEN+G: 5-week ramp up of venetoclax to 400mg QD + obinutuzumab 1000mg day 1/8/15 in clcle 1 and day 1 for 6 cycle Vs Chlorambucil+G: chlorambucil 0.5mg/kg day 1/15 for 12 cycle + obinutuzumab 1000mg day 1/8/15 in clcle 1 and day 1 for 6 cycle	VEN: 5-week ramp up of venetoclax to 400mg QD Ibrutinib: 420mg QD
ORR	80% (2008 IWCLL)	92% vs 72% (2008 IWCLL)	61.2% vs 61.5% *(CR+CRh)*	*43% (CR+CRh)*	85% vs 71% (2008 IWCLL)	100% (11/11) (undetectable MRD rates of 75%(PB) and 72%(BM))
CR	*8% (CR+CRi)*	*8% vs 4% (CR+CRi)*	-	-	*50% vs 23% (CR+CRi)*	*55% (CR+CRi)*
PR	*73% (nPR+PR)*	*84% vs 69% (nPR+PR)*	-	-	*35% vs 48%*	*45%*
SD	-	-	-	-	-	-
DCR	-		-	-	-	-
m Follow-up	22m	22.9m	7.9m vs 11m	6.5m	28m	-
PFS	-	NR vs 18.1m	-	-	NR vs NR	-
OS	-	NR vs NR	-	-	NR vs NR	-
DoR	Not Reached	-	-	-	-	-
Common AEs		G3 AE: 82% vs. 70.2% The most common G3 AE: Neutropenia 57.7% vs. 38.8%, Febrile neutropenia 3.6% vs. 9.6%, Infections 17.5% vs. 21.8% Death 5.2% vs. 5.9%.			The most common AE: neutropenia (60%), diarrhea (28%), fatigue (21%), nausea (19%), anemia (17%), and upper respiratory tract infection (17%). The most common G3 AE: Neutropenia 56% vs. 52%, Anemia 8% vs. 7%, Diarhea 4% vs. 1%, Vomitting 1% vs. 1%, Fatigue 2% vs. 1%, Dose interruptions due to AE 74% (Venetoclax arm) Dose reductions due to AE 21% (Venetoclax arm) Treatment discontinuation due to AE 16% (Venetoclax arm)	G3 TRAE 57% Serious TRAE 11% G3 AEs were more frequent during the first 3 cycles of combination (39%), and then decreased to 15% in the last 3-4 cycles

Source: Companies data, ASH, ASCO, EHA, ICML, CMBIS

Figure 5: BTK inhibitors under development for NHL diseases in China (as of 18 Jun 2020)

Candidates	Binding properties	Company	NHL indications						
			CLL/SLL	MCL	WM	MZL	FL	DLBCL	CNSL
Ibrutinib	Irreversible	Abbvie / JNJ	Marketed (1L)	Marketed (2L)	Marketed (2L)	-	-	Ph2 (combo, 1L)	-
Acalabrutinib	Irreversible	AstraZeneca	Ph2 (2L) Ph3 (1L)	Ph2 (2L)	-	-	-	-	-
Zanubrutinib / BGB-3111	Irreversible	BeiGene	Marketed (2L)	Marketed (2L)	Ph2 (2L)	Ph2 (2L)	Ph2 (combo, 2L)	Ph2 (2L)	-
Orelabrutinib / ICP-022	**Irreversible**	**Innocare**	**NDA (2L) P3 (1L)**	**NDA (2L)**	**Ph2 (2L)**	**Ph2 (2L)**	**P1 (combo, 2L)**	**Ph2 (2L)**	**Ph2 (2L)**
DTRMWXHS-12	-	DTRM	-	Ph1 (2L)	-	-	-	-	-
CT-1530	Irreversible	Centaurus	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	-
SHR1459	-	Hengrui	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	Ph1 (2L)	-

Source: chinadrugtrials.org.cn, insight, CMBIS

Figure 6: Adverse events of special interest

Index	Orelabrutinib N=200	Zanubrutinib N=671	Acalabrutinib N=612	Ibrutinib N=1,124
Major bleeding	0.5%	2.7%	2.0%	3.0%
Atrial fibrillation (Grade 3 or Grade 4)	0.0%	0.6%	1.0%	4.0%
Hypertension (Grade 3 or Grade 4)	2.5%	3.1%	2.5%	5.0%
Infection (>=Grade 3)	16.0%	21.3%	18.0%	24.0%
Secondary malignancy	0.5%	7.9%	10.6%	10.0%
Diarrhea	7.0%	18.2%	38.4%	39.0%

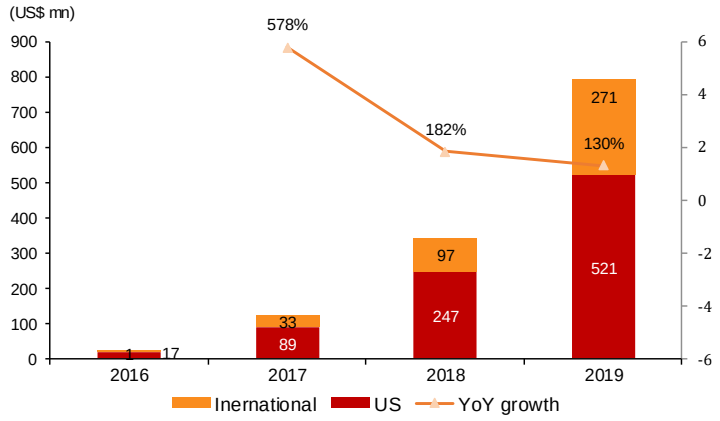
Source: Companies data, CMBIS

Figure 7: Comparison of BTK inhibitors' clinical trial data on CLL/SLL

	Orelabrutinib	Ibrutinib	Acalabrutinib	Zanubrutinib
Source	2019 ASH	2019 ASCO	2019 EHA	2019 ICML
Trial ID	ICP-CL-00103/ NCT03493217	RESONATE (PCYC-1112)/ NCT01578707	ACE-CL-309 (ASCEND)/ NCT02970318	BGB-3111-205/ NCT03206918
Indication	r/r CLL/SLL	r/r CLL/SLL	r/r CLL	r/r CLL/SLL
N (patients on BTK)	80	195	155	91
Phase	I/II	III	III	II
Line of treatment	≥2L	≥2L	⩾2L	⩾2L
Regimen	150mg BID	420mg QD	100mg BID	160mg BID
Median follow-up	8.7m	65.3m	16.1m	15.1m
ORR	88.8% (2008 IWCLL)	88.0% (2008 IWCLL)	81.0% (2008 IWCLL)	84.6% (2008 IWCLL, 2014 Lugano)
CR	*3.8%*	*11.0%*	-	*3.3%*
PR	*85.0%*	*77.0%*	-	*81.3%*
SD	5.0%	-	-	4.4%
DCR	93.8%	-	-	89.0%
PFS	-	44.1m	NR	NR
OS	-	67.7m	12m-OS: 94% vs 91%	-
Discontinue due to AEs	3.8%	16%	11%	8.8%
Common AEs	**The most common AE**: *thrombocytopenia, neutropenia, anemia, respiratory system infections, and purpura* **The most common SAE**: *neutropenia, thrombocytopenia, lung infection*	**The most common AE** (>20%): *diarrhea, fatigue, pyrexia, and nausea* **The most common SAE**: *neutropenia, pneumoni, Atrial fibrillation, Pyrexia*	**The most common AE**: *headache (22%), neutropenia (19%), diarrhea (18%), anemia (15%), and cough (15%)* **The most common SAE**: *neutropenia (16%), anemia (12%), and pneumonia (5%); with rituximab/idelalisib, neutropenia (40%) and diarrhea (24%)*	**The most common AE**: *decrease (68.1%), upper respiratory tract infection (45.1%), purpura (34.1%), and platelet count decreased (33.0%)* **The most common SAE**: *neutrophil count decrease (44.0%), lung infection (9.9%), upper respiratory tract infection (9.9%), platelet count decrease (8.8%), and anemia (8.8%)*

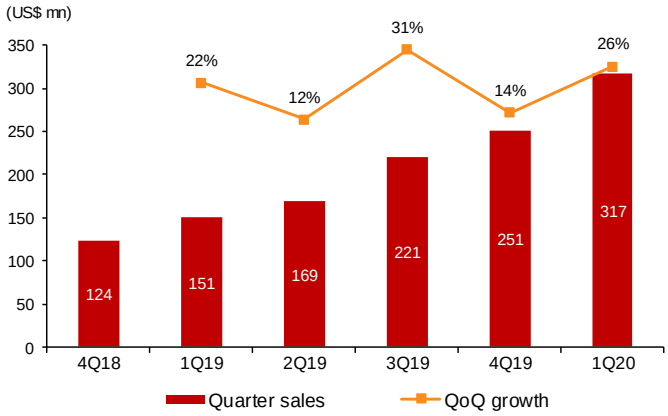
Source: Companies data, ASH, ASCO, EHA, ICML, CMBIS

Figure 8: Global sales trend for Venetoclax (2016-2018)



Source: Abbvie, CMBIS

Figure 9: Global sales of Venetoclax by quarter



Source: Abbvie, CMBIS

Figure 10: Key pipeline of Ascentage

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

Source: Company data, CMBIS

Financial Summary

Income statement

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Revenue	**7**	**15**	**7**	**7**	**152**
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	(46)
Gross profit	**7**	**12**	**7**	**7**	**106**
Other income	61	49	19	19	19
Selling & distribution expenses	0	0	0	0	(76)
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)**	**(739)**
Other expenses	(38)	(914)	0	0	0
Finance costs, net	(37)	(4)	(16)	(48)	(84)
Pre-tax profit	**(347)**	**(1,482)**	**(729)**	**(794)**	**(822)**
Income tax	2	2	0	0	0
Minority interests	0	0	0	0	0
Net profit (Net loss)	**(345)**	**(1,481)**	**(729)**	**(794)**	**(822)**

Cash flow summary

YE 31 Dec (RMB mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Profit before tax	**(347)**	**(1,482)**	**(729)**	**(794)**	**(822)**
Depreciation & amortization, etc.	18	26	24	63	102
Change in working capital	27	15	(13)	0	(30)
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
Righ-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**	**197**
Inventories	0	0	0	0	13
Trade receivables	0	0	0	0	25
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**	**2,596**
Bank loans	38	92	692	1,692	2,492
Trade payables	5	13	0	0	8
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)**	**(1,455)**
Minority interest	**0**	**0**	**0**	**0**	**0**
Shareholders' equity	**(1,012)**	**890**	**162**	**(633)**	**(1,455)**

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	5
Total	100	100	100	100	5
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	216
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)	(3.94)
DPS (RMB)	0.00	0.00	0.00	0.00	0.00
BVPS (RMB)	N/A	Net	1.61	7.27	11.34

Source: Company data, CMBIS estimates

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