

Biotech Sector

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DBS Group Research . Equity

30 Jun 2022

Time to bottom fish

- **Biotech stocks listed in HK dropped 58% in 1 yr, close to historical trough; stocks dual listed in the US dropped deeper, time to bottom fish**
- **Buy [BeiGene \(6160 HK\)](#) as market ignores two positives 1) unlike most Chinese peers, it can penetrate the US – one of the few market where prices can be raised; 2) It can keep its US listing while many peers will be delisted**
- **Catalysts ahead - expect BeiGene to obtain US approval for launch of two innovative products in July and Oct**

Negatives largely priced in. The Hang Seng HK Listed Biotech Index has dropped by 58% in the last 12 months, steeper than the 36% decline in the Nasdaq biotech index, due to price cuts and tightened clinical trial procedures in China, rejection of launch of Chinese drugs in the US, and possible delisting of selected stocks in the US. Trading at an enterprise value ("EV", mkt cap +net debt or -net cash) to FY22 sales 84% below the global average, negatives are largely priced in and it is now time to bottom fish.

BUY BeiGene (6160 HK) as it can make inroads into the US market. While many countries have been lowering drug prices, drug prices in the US have been rising by 4-10% p.a. during 2016-20. Thus, entry into the US is crucial for sales growth. Since the rejection by the US authorities of two innovative drugs of two Chinese players (Innovent 1801 HK and HutchMed 13 HK) in 1H22, the market is concerned that Chinese players cannot make inroads into the US. We note that the reason for the rejection was the absence of US patients in their clinical trials. BeiGene has the largest number of clinical trials (phases 2 & 3) including US patients at 22 vs 1 to 6 for major Chinese peers. We expect BeiGene will obtain approvals for its oncology products for launch in Jul and Oct as 10-21% of patients in those trials are from the US, and the efficacy improvement relative to competing drugs is 7-54% based on available clinical data.

Despite market concerns, we believe BeiGene will keep its listed status in the US unlike many Chinese peers. The US has identified 150 US-listed Chinese companies as potential targets for delisting as the US thinks their financial reports are unable to be inspected. Out of 15 Chinese biotech firms listed in the US, BeiGene is one of 3 that have changed their principal auditor to an US firm, adopted the same practices of US firms with businesses in China like Texas Instrument (TXN US). As the auditor is located in the US, the authorities are able to inspect BeiGene's financials. Trading at 9.5x EV to FY22F sales which is historical low, the valuation is attractive.

HSI: 21,997

ANALYST

Mark Kong +852 36684187 mark_kong@dbs.com
Nico Chen +852 36684171 nicochen@dbs.com

Recommendation & valuation

Company Name	Price HK\$	Target Price HK\$	Recom	Mkt Cap US\$m	PE 23F x
BeiGene (6160 HK)	100.20	166.00	BUY	17,155	n.a.
CSPC Pharmaceutical (1093 HK)	7.63	11.50	BUY	11,604	11.0
Shanghai Henlius Biotech 'H' (2696 HK)	17.40	30.04	BUY	1,205	175.2

Source: Thomson Reuters, DBS Bank (Hong Kong) Limited ("DBS HK")



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Time to bottom fish biotech stocks listed in Hong Kong

The biotech stocks listed on the Hong Kong Stock Exchange have corrected drastically in the last 12 months. The Hang Seng Hong Kong Listed Biotech Index (comprising 59 companies) has corrected by 58% from the peak in 2021, while the magnitude of the drop was much larger in the Nasdaq Biotech Index (-36%) and CSI 800 Pharmaceutical & Biotechnology Index (-37%). The reasons:

- 1) China had tightened the requirement for clinical trials which raises the cost of development of new drugs.

Example 1: In Nov 2021, the Centre for Drug Evaluation (CDE) issued a new guideline for clinical trials of oncology drugs requiring the developer to prove the drug can provide better efficacy or safety than the current drugs available for the same indication, otherwise there is no value to the patient. This guideline increases the difficulty to gain approval.

Example 2: In Dec 2021, CDE issued a new requirement that, unless the innovative drug developer states that the drug is not suitable for children, the clinical trial must include children. This will increase the cost of clinical trials.

- 2) Ongoing price cuts imposed by the China government in regional / National tenders. Since 2018, National Healthcare Security Administration has arranged six rounds of National tenders for drugs, and the average price cut has been 53%. This will continue as the government targets to raise the percentage of drugs procured for public medical institutes through the provincial / National tender platform from 75% in 2020 to 90% in 2025.
- 3) Chinese pharmaceutical companies' penetration into the US market seems more difficult after the US Food & Drug Administration (FDA) rejected the application for launch of two innovative drugs by Innovent (1801 HK) and Hutchmed (13 HK) in 1H22, namely, Sintilimab and Surufatinib (see: [U.S. FDA declines to approve two more China-tested drugs | Reuters](#)). From a global perspective, the US is a very attractive market for drugs as it is one of the very few markets where drug prices can be raised based on the figures in 2016-20 (see the table "Annual average change of drugs price").

- 4) Mandatory delisting from the US stock exchanges, as directed by the US government. There are many Chinese biotech companies with a dual listing in Hong Kong / mainland China and the US. After the Holding Foreign Companies Accountable Act was effective in 2020 in the US, the US Securities & Exchange Commission (SEC) can delist companies located in a foreign jurisdiction if it thinks the Public Company Accounting Oversight Board in the US is unable to inspect or investigate the financials. As of 21 June 2022, 150 companies have been identified for possible delisting (see: [SEC.gov | Holding Foreign Companies Accountable Act \("HFCAA"\)](#)), and many Chinese biotech companies like BeiGene (6160 HK, BGNE US) and Zai Lab (9688 HK, ZLAB US) are on the list. Investors may sell those shares given the uncertainties, resulting in pressure on this sector.
- 5) Interest rate hikes in developed countries. This would drag down the valuation of biotech companies. This is because a major way to value biotech companies is to sum up the estimated cash flow their drugs can generate in future and then discount the cashflows into present value. The discount rate is pegged to interest rate. The higher the interest rate, the higher the discount rate, which would lower the present value.

Annual average change of drugs prices

Annual average change of drugs price	2016	2017	2018	2019	2020
U.S.	7.6%	6.0%	5.9%	10.3%	4.2%
U.K.	-1.4%	-0.2%	-0.2%	0.5%	0.1%
Switzerland	-1.1%	-2.4%	-2.6%	-2.9%	-2.6%
Sweden	10.9%	-3.9%	-3.8%	-4.5%	-0.7%
Germany	-10.9%	-10.4%	-10.5%	-0.9%	-1.2%
Italy	-3.4%	-3.2%	-3.1%	-0.3%	0.1%
France	-5.7%	-5.2%	-5.2%	-4.9%	-1.7%
Canada	-0.5%	-0.3%	-0.4%	0.9%	0.9%

Source: [Annual Reports - Canada.ca](#)

After the deep correction, negatives are largely priced in. Hang Seng Hong Kong listed Biotech Index are now trading close to its seven-year's trough. Relative to peers in many other regions, in terms of enterprise value (market cap minus net cash or add net debt) to FY22F sales, the HK-listed biotech stocks are trading at discounts of 29% - 84% (see the table "Bio & pharm sector: enterprise value /FY22F

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sales). At such a deep valuation discount, we think it is time to consider bottom fishing.

Hang Seng Hong Kong Listed Biotech Index



Source: Bloomberg Finance L.P.

Bio & pharm sector valuation: enterprise value / FY22F sales

Location of stock exchange(s)	No. of company	EV / Best 22F sales (mkt cap weighted)	EV / Best 22F sales (simple average)
Hong Kong	55	8	6
Mainland China	103	11	8
U.S.	457	32	104
South Korea	31	17	5
India	38	4	3
Taiwan	8	6	7
Japan	48	4	17
Western Europe	165	6	13
Australia	23	12	189
Average		11	39
Hong Kong's discount to average		-29%	-84%

Source: Bloomberg Finance L.P. (21 Jun 2022)

Bottom fish BeiGene (6160 HK)

The uncertainties have dragged the performance of biotech stocks. Thus, we should bottom fish stock (s) that are able to mitigate the risks above. Thus, our criteria are:

- 1) Able to penetrate into the US market. As mentioned above, it is easier to raise drug prices in the US. Larger revenue contribution from the US could mitigate the impact of price cuts in China.

To judge if a company has this ability, we look at the number of clinical trials it has running in the US or having the US as one of the locations for the trial. This is crucial, as the reason that the product launch of Innovent and Hutchmed were rejected by the US FDA was that the clinical data was taken solely from China, and was not representative for patients in the US. Thus, including US patients is crucial.

- 2) Biotech stocks with a US listing should be able to reduce the risk of being delisted due to the Holding Foreign Companies Accountable Act.

We believe BeiGene is one of the very few biotech stocks that can fulfil the criteria above, and this is not priced in.

- 1) For criteria 1, relative to other biotech companies listed in Hong Kong and mainland China, BeiGene has strongest ability to penetrate into the US market as it has largest number of clinical trials running in the US or with the US being one of the locations for the trial, in both phases 2 and 3 (see the table: "Major Chinese biotech companies: number of clinical trials conducted in U.S."). In terms of number of drugs and indications involved, it is also the largest.

Among the trials of BeiGene carried out in the US, six demonstrated superior efficacy or safety over major competing drugs based on available clinical data (see the table "Superiority of BeiGene major products"). The yellow highlights are areas where the drugs are superior.

Four drugs are said to address two targets and are potentially promising, namely, TIGIT and TIM-3 (see the table "BeiGene clinical trial on TIGIT and TIM-3"). The target is a molecule in the body, usually a protein, that is intrinsically associated with a particular disease process, which could be addressed by a drug to produce the desired therapeutic effect. These drugs are potentially promising because they are possibly much better than competing drugs for a particular indication. The TIM-3 protein appears in multiple cells (e.g. T-cells, dendritic cells, macrophages, myeloid-derived suppressors cells, natural killer cells). As a result, the drug should be able to find this protein easily in the human body, making it easier to have an impact on the disease. For TIGIT, in Roche (ROG SW)'s phase 2 clinical trial for 1st line treatment of

metastatic non-small cell lung cancer with high expression of PD-L1, it showed much higher objective response rate (“ORR”) relative to competing therapy (anti-PD-L1 monotherapy, 69% vs 24.1%),

Other than the trials above, trials involving the US as a location, completed and pending for U.S. FDA approval in 2022 are crucial for share price performance. There are two: A) Tislelizumab (PD1 antibody) for 2nd line treatment of Esophageal squamous cell carcinoma (ESCC). The U.S. FDA is committed to respond in Jul; and B) Zanubrutinib for treatment of chronic lymphocytic leukemia / small lymphocytic lymphoma (CLL/SLL). The U.S. FDA is committed to respond in Oct. We believe these drugs are likely to obtain the approval. Firstly, unlike Sintilimab by Innovent and Surufatinib by Hutchmed, which solely rely on China clinical data, BeiGene has included US persons in its trials. Thus, we believe there is high chance of obtaining approval from the U.S. FDA (see the table: “BeiGene: geographic breakdown of patients’ number in two clinical trials including U.S.”). Secondly, based on available clinical data, these drugs have demonstrated better efficacy over direct competitors in the targeted indications. In terms of ORR in 2nd line treatment of ESCC, Tislelizumab is higher than Pembrolizumab developed by Merck (MRK US) (20% vs 13%). In terms of ORR in treatment of CLL/SLL, Zanubrutinib is higher than Ibrutinib developed by AbbVie (ABBV US) (95% vs 89%).

- 2) On criterial 2, we believe BeiGene can avoid being delisted in the U.S. stock market as it has changed its principal auditor for financial statements to be filed with the U.S. SEC from EY China to EY U.S. in Mar 2022. As of 22 Jun 2022, it is one of the very few Chinese biotech companies listed in the US to change its principal auditor to a US-based auditor (see the table: “Principal auditor of major Chinese biotech listed in the U.S.”). By doing this, its principal auditor will be directly under the supervision of the Public Company Accounting Oversight Board in the US and it can be inspected and investigated completely by the regulatory bodies in the US. The principal auditor can review the audit working papers prepared by the local auditor(s) in China. This satisfies the U.S. SEC’s requirement to maintain its listing status. Many US companies listed in the US, with business exposure in China have adopted the same practice, e.g.

Texas Instruments (TXN US), Wynn Resorts (WYNN US). If BeiGene is delisted after the auditor change, those US companies have to be delisted too. This is very unlikely. As such, BeiGene should be able to keep its fund-raising platform in the US stock market which is important for future growth.

In terms of EV / current year projected sales (22F), BeiGene trades close to its historical trough (see the chart “BeiGene’s EV / current year projected sales”) which is a good time to consider bottom fishing.

Major Chinese biotech companies: number of clinical trials (phase 2 & 3) conducted in the US

Ticker	Name	Number of trials involving US		Number of drug/biologic		Number of indications	
		Clinical trial (Ph II)	Clinical trial (Ph III)	Clinical trial (Ph II)	Clinical trial (Ph III)	Clinical trial (Ph II)	Clinical trial (Ph III)
6160 HK Equity	BEIGENE LTD-ADR	9	13	7	7	9	12
1801 HK Equity	INNOVENT BIOLOGICS INC	2	1	2	1	2	1
1177 HK Equity	SINO BIOPHARMACEUTICAL	n/a	n/a	0	2	1	3
1877 HK Equity	SHANGHAI JUNSHI BIOSCIENCE-H	2	3	0	4	0	4
9939 HK Equity	KINTOR PHARMACEUTICAL LTD	3	2	4	1	4	1
9926 HK Equity	AKESO INC	1	1	1	1	1	1
2137 HK Equity	BRII BIOSCIENCES LTD	0	2	0	1	0	1
9995 HK Equity	REMEGEN CO LTD-H	2	0	2	0	2	0
867 HK Equity	CHINA MEDICAL SYSTEM HOLDING	2	2	4	4	5	5
9966 HK Equity	ALPHAMAB ONCOLOGY	1	0	2	0	2	0
9969 HK Equity	INNOCARE PHARMA LTD	3	0	3	0	3	0
6855 HK Equity	ASCENTAGE PHARMA GROUP INTER	6	0	9	0	6	0
2171 HK Equity	CARSGEN THERAPEUTICS HOLDING	1	0	1	0	1	0
IMAB US Equity	I-MAB-SPONSORED ADR	1	1	1	1	1	1
600276 CH Equity	JIANGSU HENGRUI MEDICINE C-A	1	3	1	3	1	3
600196 CH Equity	SHANGHAI FOSUN PHARMACEUTI-A	1	2	1	1	1	2
000963 CH Equity	HUADONG MEDICINE CO LTD-A	2	1	2	1	2	1
603087 CH Equity	GAN & LEE PHARMACEUTICALS -A	0	2	0	1	0	2
002653 CH Equity	HAISCO PHARMACEUTICAL GROU-A	0	1	0	1	0	1
002019 CH Equity	YIFAN PHARMACEUTICAL CO LT-A	1	2	1	1	1	1

Source: Annual reports, companies' websites, corporate presentations of the companies above, DBS HK

Superiority of BeiGene's major products

Drug	Combo with	Indication	Clinical phase	Competing drug	Stage of competing drug	Objective response rate % (7)		Complete response % (8)		Overall survival (months) (9)		Adverse event level 3 or above - % in total trial patients (10)	
						Competitor	BeiGene	Competitor	BeiGene	Competitor	BeiGene	Competitor	BeiGene
Zanubrutinib	(Mono)	1L & R/R WM (1)	3	Ibrutinib	Launched	93	94	19	28	93	97	63	58
Zanubrutinib	(Mono)	R/R CLL/SLL (2)	3	Ibrutinib	Launched	63	78	2	2	92	97	51	56
Zanubrutinib	Venetoclax (Bcl-2 inhibitor)	1L CLL/SLL (3)	3	Ibrutinib + Venetoclax	Clinical trial Ph2	87	97	69	13	96	96	-51	37
Zanubrutinib	(Mono)	R/R MZL (4)	2	Ibrutinib	Launched	58	68	10	26	-85	95	71	40
Zanubrutinib	Obinutuzumab (anti-CD20)	R/R FL (5)	2	Acalabrutinib + Rituximab	Clinical trial Ph1	39	72	8	39	85	85	>14	>14
Tislelizumab	Chemotherapy	1L advanced ESCC (6)	3	Pembrolizumab + Chemotherapy	Clinical trial Ph3	45	47	0	0	26	26	72	87

Source: <https://ashpublications.org>, <https://ascopost.com>, <https://aacrjournals.org>, American Society of Clinical Oncology

1L & R/R WM (1): 1st line treatment for Waldenstrom macroglobulinemia. 1st line therapy is the one accepted as the best treatment. Subsequent treatment(s) may be used (i.e. 2nd line, 3rd line). R/R refers to relapsed / refractory.

R/R CLL/SLL (2): relapsed / refractory chronic lymphocytic leukaemia / small lymphocytic lymphoma

1L CLL/SLL (3): 1st line treatment for chronic lymphocytic leukaemia / small lymphocytic lymphoma

R/R MZL (4): relapsed / refractory marginal zone lymphoma

R/R FL (5): relapsed / refractory follicular lymphoma

1L advanced ESCC (6): 1st line treatment for advanced Esophageal Squamous-Cell Carcinoma

Objective response rate % (7): The proportion of patients with tumor size reduction of a predefined amount and for a minimum time period. Response duration usually is measured from the time of initial response until documented tumor progression.

Complete response % (8): The disappearance of all signs of cancer in response to treatment. This does not always mean the cancer has been cured.

Progression free survival (months) (9): The length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works.

Overall survival (months) (10): The length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive. In a clinical trial, measuring the overall survival is one way to see how well a new treatment works

Adverse event level 3 or above - % in total trial patients (11): Severe or medically significant but not immediately life threatening; hospitalization of prolongation of hospitalization indicated; disabling; limiting self-care ADL. Above level 3 is life threatening.

BeiGene: clinical trials on TIGIT and TIM-3

Drug	Combo with	Indication	Clinical phase	Target 1	Target 2
Ociperlimab	Tislelizumab	1L PD-L1 high advanced NSCLC (1)	3	TIGIT	PD1
Ociperlimab	Tislelizumab + Chemotherapy	1L NSCLC	2	TIGIT	PD1
Ociperlimab	Tislelizumab + Concurrent Chemoradiotherapy	LA NSCLC (2)	2	TIGIT	PD1
Surzbeciclimab	Tislelizumab	Advanced solid tumors	2	TIM-3	PD1

Source: <https://ascopubs.org>, <https://www.cancernetwork.com>, <https://www.annalsofoncology.org>

1L PD-L1 high advanced NSCLC (1): 1st line treatment for advanced non-small cell lung cancer with high expression of PD-L1

LA NSCLC (2): locally advanced non-small cell lung cancer

BeiGene: geographic breakdown of the number of patients in two clinical trials including the US

Tislelizumab (mono) - 2L ESCC	Patient number	Percentage
Asia (excluding Japan)	354	69%
Japan	50	10%
US/EU	108	21%
Total	512	100%

Zanubrutinib (mono) - CLL/SLL	Patient number	Percentage
Australia	33	30%
Austria	4	4%
Belgium	1	1%
Chinese Taipei	1	1%
Czech Republic	5	5%
France	5	5%
Italy	10	9%
New Zealand	12	11%
Poland	5	5%
Russia	6	6%
Sweden	8	7%
UK	7	6%
US	12	11%
Total	109	100%

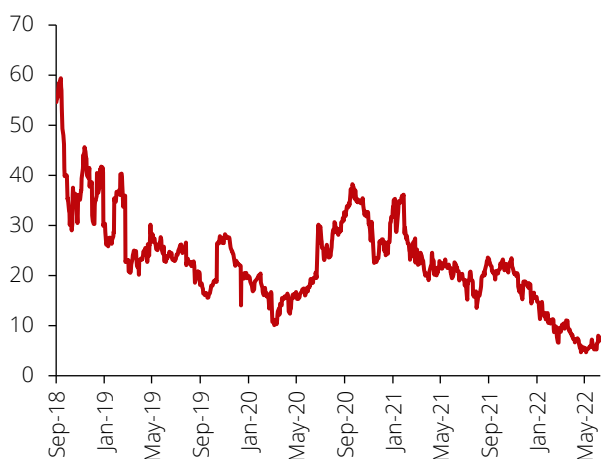
Source: <https://ascopubs.org/doi/abs/10.1200/JCO.21.01926>; <https://haematologica.org/article/view/haematol.2020.259432>

Principal auditor of major Chinese biotech companies listed in the US

Principal auditor for financial statements to be filed with U.S. SEC				
Biotech Company		FY2021 financial statement	Current	Status as of 24 June 2022
BeiGene, Ltd.	BGNE US	EY China	EY US	Changed
Zai Lab Limited	ZLAB US	Deloitte China	KPMG US	Changed
Legend Biotech Corporation	LEGN US	EY China	EY US	Changed
HUTCHMED (China) Limited	HCM US	PwC China	PwC China	Evaluating
CASI Pharmaceuticals, Inc.	CASI US	KPMG China	KPMG China	Evaluating
Connect Biopharma	CNTB US	PwC China	PwC China	Evaluating
Adagene Inc.	ADAG US	PwC China	PwC China	Evaluating
I-Mab	IMAB US	PwC China	PwC China	Evaluating
Sinovac Biotech Ltd.	SVA US	Grant Thornton China	Grant Thornton China	Evaluating
Green Vision Biotechnology Corp.	GVBT US	Centurion ZD HK	Centurion ZD HK	No announcement
BeyondSpring Inc.	BYSI US	EY China	EY China	No announcement
JRSIS Health Care Corporation	JRSS US	Centurion ZD HK	Centurion ZD HK	No announcement
Gracell Biotechnologies Inc.	GRCL US	PwC China	PwC China	No announcement
Burning Rock Biotech Limited	BNR US	EY China	EY China	No announcement
Genetron Holdings Limited	GTH US	PwC China	PwC China	No announcement

Source: www.sec.gov, Annual reports and websites of the companies above

BeiGene's EV / current year projected sales



Source: Thomson Reuters

Contract development & manufacturing organizations (CDMO) can penetrate into the US with biotech firms.

Both Chinese contract research organizations (“CRO”, providing R&D services to pharm companies) and CDMO (providing products manufacturing services to pharm companies) with U.S. exposure can ride on Chinese pharm products’ penetration into the US market to grow.

In this sub-segment, we prefer CDMOs that generate over half of their revenue by providing manufacturing services to medical products in commercialization stage or late stage of clinical trials. Their revenue growth is more certain because:

- 1) The most uncertain stage of medical product development is pre-clinical exploration and clinical trial due to higher failure rate. It is over 92% for pre-clinical and phase 1, over 84% in phase 2, over 47% in phase 3, according to Biotechnology Innovation Organization. The pharm company can stop the project at any time and revenue of the CRO or CDMO serving early clinical stage products

will be impacted. In commercialization stage, all the clinical trials are done and hence uncertainty is low. The pharm company is keen to ramp up production to generate revenue, after spending huge amounts of money on R&D for years. CDMOs will ride on the growth.

- 2) The risk of medical products in late stage of clinical trial is much lower due to the lower failure rate as mentioned. So, CDMOs servicing this part is in a safer position relative to early stage.

Among the listed Chinese CDMOs (see the table “Listed Chinese CDMO comparison”), we think Asymchem (6821 HK) and Porton (300363 CH) are in better position as they generate >50% of their revenue by providing manufacturing services to medical products in commercialization stage or late stage of clinical trial. Asymchem is in an even better position than Porton due to higher order backlog to annual sales ratio (2.7x vs 1.8x), which implies higher certainty in revenue growth in future.

Comparison of listed Chinese CDMOs

	21A sales (Rmb bn)	% of sales from clinical trial late stage / commercialization services	% of sales from overseas	Order backlog based on 21A annual report (Rmb bn)	Order backlog / 21A sales	Production site in US	22F PE (x)
Asymchem (6821 HK)	4.6	54%	86%	12.7	2.7	Y	24
Porton (300363 CH)	3.1	66%	78%	5.6	1.8	Y	29
Zhejiang Jiuzhou (603456 CH)	4.1	n/a	72%	n/a	n/a	Y	45
PharmaBlock (300725 CH)	1.2	Not much(estimated)	70%	n/a	n/a	Y	48
BrightGene (688166 CH)	1.1	83%(estimated)	88%	n/a	n/a	n/a	30

Source: Bloomberg Finance L.P., 2021 annual report of the companies above, companies’ websites

DBS HK recommendations are based on an Absolute Total Return* Rating system, defined as follows:

STRONG BUY (>20% total return over the next 3 months, with identifiable share price catalysts within this time frame)

BUY (>15% total return over the next 12 months for small caps, >10% for large caps)

HOLD (-10% to +15% total return over the next 12 months for small caps, -10% to +10% for large caps)

FULLY VALUED (negative total return, i.e., > -10% over the next 12 months)

SELL (negative total return of > -20% over the next 3 months, with identifiable share price catalysts within this time frame)

*Share price appreciation + dividends

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Sources for all charts and tables are DBS HK unless otherwise specified.

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DBS Bank (Hong Kong) Limited

13th Floor One Island East, 18 Westlands Road, Quarry Bay, Hong Kong

Tel: (852) 3668-4181, Fax: (852) 2521-1812

DBS Regional Research Offices

HONG KONG

DBS Bank (Hong Kong) Ltd

Contact: Dennis Lam

13th Floor One Island East,

18 Westlands Road, Quarry Bay, Hong Kong

Tel: 852 3668 4181

Fax: 852 2521 1812

e-mail: dbsvhk@dbs.com

SINGAPORE

DBS Bank Ltd

Contact: Paul Yong

12 Marina Boulevard,

Marina Bay Financial Centre Tower 3

Singapore 018982

Tel: 65 6878 8888

e-mail: groupresearch@dbs.com

Company Regn. No. 196800306E

INDONESIA

PT DBS Vickers Sekuritas (Indonesia)

Contact: Maynard Priajaya Arif

DBS Bank Tower

Ciputra World 1, 32/F

Jl. Prof. Dr. Satrio Kav. 3-5

Jakarta 12940, Indonesia

Tel: 62 21 3003 4900

Fax: 6221 3003 4943

e-mail: indonesiaresearch@dbs.com

THAILAND

DBS Vickers Securities (Thailand) Co Ltd

Contact: Chanpen Sirithanarattanakul

989 Siam Piwat Tower Building,

9th, 14th-15th Floor

Rama 1 Road, Pathumwan,

Bangkok Thailand 10330

Tel. 66 2 857 7831

Fax: 66 2 658 1269

e-mail: research@th.dbs.com

Company Regn. No 0105539127012

Securities and Exchange Commission, Thailand