Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

NOMURA
EQUITY RESEARCH

F12 – good progress, expect a F13 EMA decision

Vitiligo market is underserved in our view – CUV's potential product addresses this

August 29, 2012

Rating Remains	**Buy**
Target price Increased from 3.34	AUD 3.38
Closing price August 29, 2012	AUD 1.63
Potential upside	+107.4%

Action: FY12 loss in line with forecasts

CUV's FY12 NPAT was -A$9.8mn (vs. Nomura at -A$9.8mn). Differences compared to our forecasts included slightly lower-than-expected revenue.

Catalyst: CUV moving into Vitiligo market

CUV aims to show that its lead compound, afamelanotide, has efficacy against several sun-related diseases. CUV has previously announced that it is investigating the effectiveness of afamelanotide in Non-Segmental Vitiligo, a condition that affects up to 45mn people globally. CUV plans to use afamelanotide as an adjunct to the current mainstay of treatment, narrow band UVB (NB-UVB), as well as testing afamelanotide as a single treatment option. In early Phase II trial results presented at a recent conference, the NB-UVB plus afamelanotide group showed earlier onset of repigmentation compared to controls.

FY12 – positive Phase III for EPP

CUV previously announced that final analyses of its confirmatory Phase III European study (CUV029) in erythropoietic protoporphyria (EPP) have shown a clinically relevant, statistically significant prophylactic treatment effect for patients who had been administered its afamelanotide drug.

Valuation: TP AUD3.38 (from AUD3.34), Buy maintained

We make no changes to our model assumptions in terms of the take-up of afamelanotide in its major markets, but have 1) incorporated FY12 actuals and 2) revised future interest revenue in line with the FY12 result. Hence, our target price has increased to AUD3.38 per share from AUD3.34.

30 Jun	FY12		FY13F		FY14F		FY15F
Currency (AUD)	Actual	Old	New	Old	New	Old	New
Revenue (mn)	1	4	4	8	8		22
Reported net profit (mn)	-10	-10	-10	-8	-8		0
Normalised net profit (mn)	-10	-10	-10	-8	-8		0
FD normalised EPS	-31.75c	-29.54c	-29.43c	-21.33c	-21.68c		0.95c
FD norm. EPS growth (%)	na	na	na	na	na		na
FD normalised P/E (x)	na	N/A	na	N/A	na	N/A	>100
EV/EBITDA (x)	na	N/A	na	N/A	na	N/A	na
Price/book (x)	4.1	N/A	16.4	N/A	>100	N/A	68.7
Dividend yield (%)	na	N/A	na	N/A	na	N/A	na
ROE (%)	-65.0	-135.8	-119.5	-757.8	-396.4		49.8
Net debt/equity (%)	net cash	net cash	net cash	net cash	net cash		net cash

Source: Company data, Nomura estimates

Key company data: *See page 2 for company data and detailed price/index chart.*

Anchor themes

We continue to believe that there is a very high possibility of CUV getting afamelanotide to the market. This points to cashflow from sales, and sooner than for most other biotechnology companies.

Nomura vs consensus

There are no consensus figures.

Research analysts

Australia Health Care & Pharmaceuticals

Dr David Stanton - NAL

Zara Lyons - NAL

See Appendix A-1 for analyst certification, important disclosures and the status of non-US analysts.

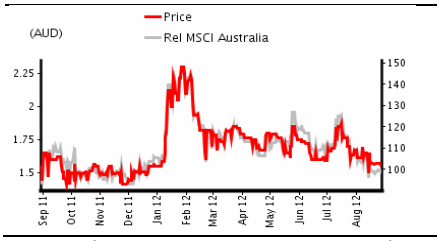
Key data on Clinuvel Pharmaceuticals

Income statement (AUDmn)

Year-end 30 Jun	FY11	FY12	FY13F	FY14F	FY15F
Revenue	**1**	**1**	**4**	**8**	**22**
Cost of goods sold	0	0	-1	-3	-8
Gross profit	**1**	**1**	**3**	**5**	**14**
SG&A	-14	-11	-13	-14	-14
Employee share expense					
Operating profit	**-13**	**-10**	**-11**	**-8**	**-1**
EBITDA	**-13**	**-10**	**-11**	**-8**	**0**
Depreciation	0	0	0	0	0
Amortisation	0	0	0	0	0
EBIT	-13	-10	-11	-8	-1
Net interest expense	1	1	1	1	1
Associates & JCEs					
Other income	0	0	0	0	0
Earnings before tax	**-11**	**-10**	**-10**	**-8**	**1**
Income tax	0	0	0	0	0
Net profit after tax	**-11**	**-10**	**-10**	**-8**	**0**
Minority interests	0	0	0	0	0
Other items					
Preferred dividends					
Normalised NPAT	**-11**	**-10**	**-10**	**-8**	**0**
Extraordinary items	0	0	0	0	0
Reported NPAT	**-11**	**-10**	**-10**	**-8**	**0**
Dividends	0	0	0	0	0
Transfer to reserves	**-11**	**-10**	**-10**	**-8**	**0**
Valuation and ratio analysis					
Reported P/E (x)	na	na	na	na	>100
Normalised P/E (x)	-4.3	-5.1	-5.5	-7.5	172.4
FD normalised P/E (x)	na	na	na	na	>100
FD normalised P/E at price target (x)	na	na	na	na	>100
Dividend yield (%)	na	na	na	na	na
Price/cashflow (x)	na	na	na	na	3.1
Price/book (x)	3.0	4.1	16.4	>100	68.7
EV/EBITDA (x)	na	na	na	na	na
EV/EBIT (x)	na	na	na	na	na
Gross margin (%)	100.0	100.0	64.8	63.7	62.6
EBITDA margin (%)	-1,205.8	-1,421.7	-254.6	-98.9	-2.2
EBIT margin (%)	-1,214.6	-1,430.3	-255.9	-99.6	-2.5
Net margin (%)	-1,096.0	-1,351.3	-242.5	-93.4	1.7
Effective tax rate (%)	na	na	na	na	30.0
Dividend payout (%)	na	na	na	na	0.0
Capex to sales (%)	6.7	0.6	2.7	1.4	0.6
Capex to depreciation (x)	0.8	0.1	2.0	2.0	2.0
ROE (%)	-53.3	-65.0	-119.5	-396.4	49.8
ROA (pretax %)	-139.9	-183.6	-187.8	-75.3	-2.3
Growth (%)					
Revenue	na	-30.6	481.7	101.1	157.4
EBITDA	na	na	na	na	na
EBIT	na	na	na	na	na
Normalised EPS	na	na	na	na	na
Normalised FDEPS	na	na	na	na	na
Per share					
Reported EPS (AUD)	-37.58c	-31.75c	-29.43c	-21.68c	0.95c
Norm EPS (AUD)	-37.58c	-31.75c	-29.43c	-21.68c	0.95c
Fully diluted norm EPS (AUD)	-37.58c	-31.75c	-29.43c	-21.68c	0.95c
Book value per share (AUD)	0.54	0.39	0.10	0.01	0.02
DPS (AUD)	0.00	0.00	0.00	0.00	0.00

Source: Company data, Nomura estimates

Relative performance chart (one year)



Source: ThomsonReuters, Nomura research

(%)	1M	3M	12M
Absolute (AUD)	0.0	-8.4	5.8
Absolute (USD)	-1.1	-3.7	3.4
Relative to index	-3.3	-14.9	3.2
Market cap (USDmn)	61.6		
Estimated free float (%)	100.0		
52-week range (AUD)	2.31/1.4		
3-mth avg daily turnover (USDmn)	0.03		

Source: Thomson Reuters, Nomura research

Notes

Revenues started for CUV in FY11

Cashflow (AUDmn)

Year-end 30 Jun	FY11	FY12	FY13F	FY14F	FY15F
EBITDA	-13	-10	-11	-8	0
Change in working capital	3	3	5	6	20
Other operating cashflow	0	-3	1	1	1
Cashflow from operations	**-9**	**-10**	**-5**	**-2**	**20**
Capital expenditure	0	0	0	0	0
Free cashflow	**-10**	**-10**	**-5**	**-2**	**20**
Reduction in investments	0	0	0	0	0
Net acquisitions	3	5	0	0	0
Reduction in other LT assets	0	0	0	0	0
Addition in other LT liabilities	0	0	0	0	0
Adjustments	0	0	0	0	0
Cashflow after investing acts	**-7**	**-5**	**-5**	**-2**	**20**
Cash dividends	0	0	0	0	0
Equity issue	0	6	0	5	0
Debt issue	0	0	0	0	0
Convertible debt issue					
Others	0	0	0	0	0
Cashflow from financial acts	**0**	**6**	**0**	**5**	**0**
Net cashflow	**-7**	**1**	**-5**	**3**	**20**
Beginning cash	19	12	13	8	11
Ending cash	12	13	8	11	31
Ending net debt	-12	-13	-8	-11	-31

Source: Company data, Nomura estimates

Notes

CUV has performed a capital raising in FY12

Balance sheet (AUDmn)

As at 30 Jun	FY11	FY12	FY13F	FY14F	FY15F
Cash & equivalents	12	13	8	11	31
Marketable securities	0	0	0	0	0
Accounts receivable	1	1	6	12	30
Inventories	0	0	0	0	0
Other current assets	7	2	2	2	2
Total current assets	**20**	**16**	**16**	**25**	**63**
LT investments	0	0	0	0	0
Fixed assets	0	0	0	0	0
Goodwill	0	0	0	0	0
Other intangible assets	0	0	0	0	0
Other LT assets	0	0	0	0	0
Total assets	**20**	**16**	**16**	**25**	**64**
Short-term debt	0	0	0	0	0
Accounts payable	3	2	12	24	63
Other current liabilities	0	0	0	0	0
Total current liabilities	**4**	**2**	**12**	**25**	**63**
Long-term debt	0	0	0	0	0
Convertible debt					
Other LT liabilities	0	0	0	0	0
Total liabilities	**4**	**2**	**12**	**25**	**63**
Minority interest	0	0	0	0	0
Preferred stock	0	0	0	0	0
Common stock	113	119	119	124	124
Retained earnings	-100	-108	-118	-126	-125
Proposed dividends					
Other equity and reserves	3	2	2	2	2
Total shareholders' equity	**16**	**14**	**3**	**1**	**1**
Total equity & liabilities	**20**	**16**	**16**	**25**	**64**
Liquidity (x)					
Current ratio	5.36	6.76	1.26	1.01	1.01
Interest cover	na	na	na	na	na
Leverage					
Net debt/EBITDA (x)	na	na	na	na	na
Net debt/equity (%)	net cash	net cash	net cash	net cash	net cash
Activity (days)					
Days receivable	234.3	501.5	298.0	380.8	353.1
Days inventory	na	na	0.0	0.0	0.0
Days payable	na	na	1,749.5	2,168.5	1,948.4
Cash cycle	na	na	-1,451.4	-1,787.7	-1,595.3

Source: Company data, Nomura estimates

Notes

Cash and marketable securities at the end FY12 was AUD13mn

FY12 result

CUV posted FY12A net loss of AUD9.8mn in line with our forecast of AUD9.8mn.

We make no changes to our model assumptions in terms of the take-up of afamelanotide in its major markets, but have: 1) updated for FY12 actuals; and 2) revised future interest revenue in line with the FY12A results. Changes to our forecasts are shown below.

Fig. 1: CUV – changes to forecasts

	FY12A			FY13F			FY14F		
	Fcast	Actual	Diff (%)	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)
EBIT (AUDmn)	(10.4)	(10.3)	na	(11.0)	(10.8)	na	(8.5)	(8.4)	na
NPAT (AUDmn)	(9.8)	(9.8)	na	(10.2)	(10.2)	na	(7.8)	(7.9)	na
EPS (c)	(30.0)	(31.8)	na	(29.5)	(29.4)	na	(21.3)	(21.7)	na
DPS (c)	0.0	0.0	na	0.0	0.0	na	0.0	0.0	na
Net op cash flow (AUDmn)	(10.0)	(10.0)	na	(3.6)	(5.0)	na	0.7	(1.5)	na

Source: Company data, Nomura estimates

Background

CUV aims to show that its lead compound, afamelanotide, has efficacy against several sun-related diseases. Afamelanotide is a synthetic analogue of a hormone called alpha-melanocyte-stimulating hormone, or alpha-MSH. This hormone is released when ultraviolet (UV) radiation from the sun penetrates the upper layers of skin and causes damage, stimulating melanin production in the skin.

Fig. 2: Photodermatoses

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Disorder	Wavelength (nm)	Symptoms	Prevalence
Polymorphous Light eruption	300-600	Subactute rash, itching, generalised erythema. Transient in spring, diminshing in intensity through summer	10-20% of Caucasian Population, 18% of Europeans
Actinic Prurigo (HLA positive)	300-600	Subacute rash, itching, erythema generalised	Unknown, seen in American Indian and Mexican Popn
Chronic Actinic Dermatitis			16.5 per 100,000
Solar Urticaria	350-550	Acute oedematous reaction, anaphylactic reaction to UV light, most prominent in Spring and Summer	3.1 per 100,000
Discoid Lupus Erythematosis	300-650	Chronic and Recurrent light sensitive episodes of LE on exposed body surfaces	27.7 per 100,000
Erthyropoietic Protoporphyria	408-620	Acute phototoxicity after light exposure	1 per 75,000
Congenital Erythropoietic Porphyria	410		1 per 100,000

Wavelength = corresponds to wavelength of light that at which disease is seen
Source: PubMed, Nomura research

Vitiligo

CUV has previously announced that it is investigating the effectiveness of afamelanotide in Non-Segmental Vitiligo. This is a new medical indication for afamelanotide. CUV plans to use afamelanotide as an adjunct to the current mainstay of treatment, narrowband UVB (NB-UVB), as well as testing afamelanotide as a single treatment option. NSV is a de-pigmenting disease that affects c10mn persons in the US and EU. CUV's afamelanotide is being evaluated as a combination therapy with narrowband UVB light therapy in two clinical studies in patients with NSV. In early Phase II trial results presented at a recent conference, the NB-UVB plus afamelanotide group showed earlier onset of repigmentation compared to controls.

CUV product would likely be the only branded treatment in NSV

We believe the NSV market is currently USD1.4bn pa, consisting of generic treatments and UVB. We believe the current lack of high-margin branded pharma treatments in the

Vitiligo market could mean that should it be approved, then CUV's afamelanotide would be of interest to established dermatology companies, because these companies have salesforces and associated infrastructure that already detail product to dermatologists.

Starting from potential approval in 2016F, we believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide, the total CUV NSV opportunity is worth AUD7.62/share. At the current clinical stage, this translates to a risk-weighted NPV of AUD1.63/share from NSV.

EPP

CUV has succeeded in enrolling a large number of patients into its EPP trials, considering the rarity of this disease. This may be an indication of the potential patients' willingness to participate, in our view. This is despite the fact that a patient may receive a placebo injection, and hence be subjected to high levels of pain as a part of their disease process. In our view, since high unmet medical need forms a pivotal criterion for the lead regulatory agencies during the evaluation of new therapies, this factor should assist CUV in obtaining approval for afamelanotide. Photodermatology is the subspecialty which focuses on skin disorders which are triggered or aggravated by UV or light of a particular wavelength.

In early Phase II and Phase III trials, afamelanotide has been shown to mitigate or prevent the symptoms in polymorphous light eruption, solar urticaria, and EPP. These photodermatoses vary in onset, character and severity. CUV has focussed its program on those photodermatoses which are most severe in nature and for which there is no current therapy, such as EPP. Our risk-weighted valuation for EPP is AUD1.75/share. CUV's EU registration dossier for afamelanotide in EPP was submitted on 6 February 2012. The EMA should decide whether to approve afamelanotide from 210 to 360 days after complete dossier confirmation.

Result summary

We provide a summary of the final result.

Fig. 3: ACR – result summary

Income statement (AUDmn)	1H11A	2H11A	2011A	1H12A	2H12A	2012A	1H12 on 1H11 (%)	2H12 on 2H11 (%)	FY12 on FY11 (%)
Sales revenue	0.0	1.0	1.0	0.0	0.7	0.7		(30.6)	(30.6)
Other revenue	0.2	(0.2)	0.0	0.0	(0.0)	0.0	(75.2)		
Operating EBITDA	(6.2)	(6.3)	(12.6)	(6.6)	(3.7)	(10.3)			
Depreciation	0.0	(0.1)	(0.1)	0.0	(0.1)	(0.1)			
Amortisation	0.0	(0.0)	(0.0)	0.0	(0.0)	(0.0)			
Operating EBIT	(6.2)	(6.4)	(12.6)	(6.6)	(3.7)	(10.3)			
Net interest expense	0.7	0.5	1.2	0.3	0.2	0.6	(47.8)	(56.8)	(51.8)
Pre-tax profit	(4.9)	(6.5)	(11.4)	(6.2)	(3.6)	(9.8)			
Tax	0.0	0.0	0.0	0.0	0.0	0.0			
Profit after tax	(4.9)	(6.5)	(11.4)	(6.2)	(3.6)	(9.8)			
Minorities	0.0	0.0	0.0	0.0	0.0	0.0			
Normalised NPAT	(4.9)	(6.5)	(11.4)	(6.2)	(3.6)	(9.8)			
Non-recurring items	0.0	0.0	0.0	0.0	0.0	0.0			
Reported NPAT	(4.9)	(6.5)	(11.4)	(6.2)	(3.6)	(9.8)			
Other information									
Normalised EPS (cps)	(16.0)	(21.5)	(37.6)	(20.1)	(11.7)	(31.8)			
DPS (cps)	0.0	0.0	0.0	0.0	0.0	0.0			
Average shares (mn)	30.3	30.4	30.4	30.6	30.8	30.8			
Margin / ratio analysis (%)									
EBITDA margin	na	na	na	na	na	na			
EBIT margin	na	na	na	na	na	na			
Effective tax rate	na	na	na	na	na	na			

Source: Nomura estimates, company data

Revised model assumptions

Revisions to our CUV earnings model assumptions are as follows:

- **Interest income forecasts**: We have revised the interest rate earned on cash in line with FY12A average rate, and recalculated interest income based on FY12A cash balance and our FY13F forecast cash balance.

As a result of these changes, EPS has increased by 0.1cps for FY13F, and has decreased by 0.4cps for FY14F.

3. Valuation methodology and risks

Our updated risk-weighted valuation for EPP is AUD3.38 per share (from AUD3.34 per share). CUV is already being reimbursed for its product for EPP in select EU countries, and hence the business model has been substantially de-risked, in our view.

Risks to our investment view

We believe that any delay or failure to progress in clinical trials would present downside risk to our target price. That said, faster-than-expected progression to production of CUV's photoprotective technology could provide an upside boost.

Fig. 4: CUV – Risk-weighted valuation of opportunities

Valuation of CUV R&D portfolio	Risk-weighted valuation (A$ps)	Risk-weighting (in line with Clincial trial stage) (%)	Total opportunity (A$ps)
EPP	$1.75	90%	$1.94
Non-segmental Vitiligo	$1.63	21.4%	$7.62
Valuation	**$3.38**		$9.57

Source: Nomura estimates

Appendix A-1

Analyst Certification

I, David Stanton, hereby certify (1) that the views expressed in this Research report accurately reflect my personal views about any or all of the subject securities or issuers referred to in this Research report, (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this Research report and (3) no part of my compensation is tied to any specific investment banking transactions performed by Nomura Securities International, Inc., Nomura International plc or any other Nomura Group company.

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Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 1.63	29-Aug-2012	Buy	Not rated	A4,A5,A6

A4 A Nomura Group Company had an investment banking services client relationship with the issuer during the past 12 months.

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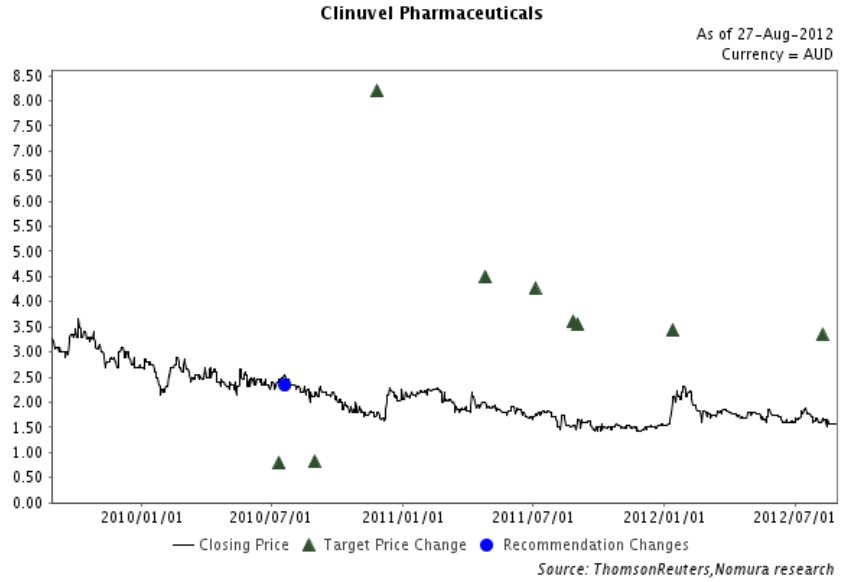
Previous Rating

Issuer name	Previous Rating	Date of change
Clinuvel Pharmaceuticals	Not Rated	12-Jul-2010

Clinuvel Pharmaceuticals (CUV AU) **AUD 1.63 (29-Aug-2012)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
08-Aug-12		3.34	1.69
12-Jan-12		3.44	1.99
02-Sep-11		3.56	1.65
26-Aug-11		3.62	1.54
04-Jul-11		4.26	1.75
26-Apr-11		4.50	2.00
26-Nov-10		8.20	1.80
30-Aug-10		0.82	2.10
12-Jul-10	Buy		2.45
12-Jul-10		0.80	2.45

For explanation of ratings refer to the stock rating keys located after chart(s)

Valuation Methodology Our risk-weighted valuation for EPP is A$1.75/share. Regarding NSV, starting from potential approval in 2016, We believe that if an eventual maximum of 10% of US and EU patients were to use afamelanotide, the risk-weighted NPV for the NSV opportunity for CUV is A$1.63/share. Our risk-weighted valuation of the CUV pipeline (A$3.38) is our TP.

Risks that may impede the achievement of the target price **We believe that any delay or failure to progress in clinical trials would present downside risk to our target price. That said, faster-than-expected progression to production of CUV's photoprotective technology could provide an upside boost.**

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Online availability of research and conflict-of-interest disclosures

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Explanation of Nomura's equity research rating system in Europe, Middle East and Africa, US and Latin America

The rating system is a relative system indicating expected performance against a specific benchmark identified for each individual stock. Analysts may also indicate absolute upside to target price defined as (fair value - current price)/current price, subject to limited management discretion. In most cases, the fair value will equal the analyst's assessment of the current intrinsic fair value of the stock using an appropriate valuation methodology such as discounted cash flow or multiple analysis, etc.

STOCKS

A rating of '**Buy**', indicates that the analyst expects the stock to outperform the Benchmark over the next 12 months. A rating of '**Neutral**', indicates that the analyst expects the stock to perform in line with the Benchmark over the next 12 months. A rating of '**Reduce**', indicates that the analyst expects the stock to underperform the Benchmark over the next 12 months. A rating of '**Suspended**', indicates that the rating, target price and estimates have been suspended temporarily to comply with applicable regulations and/or firm policies in certain circumstances including, but not limited to, when Nomura is acting in an advisory capacity in a merger or strategic transaction involving the company.
Benchmarks are as follows: **United States/Europe**: please see valuation methodologies for explanations of relevant benchmarks for stocks, which can be accessed at: http://go.nomuranow.com/research/globalresearchportal/pages/disclosures/disclosures.aspx; **Global Emerging Markets (ex-Asia):** MSCI Emerging Markets ex-Asia, unless otherwise stated in the valuation methodology.

SECTORS

A '**Bullish**' stance, indicates that the analyst expects the sector to outperform the Benchmark during the next 12 months. A '**Neutral**' stance, indicates that the analyst expects the sector to perform in line with the Benchmark during the next 12 months. A '**Bearish**' stance, indicates that the analyst expects the sector to underperform the Benchmark during the next 12 months.
Benchmarks are as follows: **United States**: S&P 500; **Europe**: Dow Jones STOXX 600; **Global Emerging Markets (ex-Asia)**: MSCI Emerging Markets ex-Asia.

Explanation of Nomura's equity research rating system in Japan and Asia ex-Japan

STOCKS

Stock recommendations are based on absolute valuation upside (downside), which is defined as (Target Price - Current Price) / Current Price, subject to limited management discretion. In most cases, the Target Price will equal the analyst's 12-month intrinsic valuation of the stock, based on an appropriate valuation methodology such as discounted cash flow, multiple analysis, etc.
A '**Buy**' recommendation indicates that potential upside is 15% or more. A '**Neutral**' recommendation indicates that potential upside is less than 15% or downside is less than 5%. A '**Reduce**' recommendation indicates that potential downside is 5% or more. A rating of '**Suspended**' indicates that the rating and target price have been suspended temporarily to comply with applicable regulations and/or firm policies in certain circumstances including when Nomura is acting in an advisory capacity in a merger or strategic transaction involving the subject company.
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SECTORS
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Target Price
A Target Price, if discussed, reflect in part the analyst's estimates for the company's earnings. The achievement of any target price may be impeded by general market and macroeconomic trends, and by other risks related to the company or the market, and may not occur if the company's earnings differ from estimates.

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