Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

NOMURA
EQUITY RESEARCH

1H13 – awaiting EMA registration decision

We believe the EMA decision is due in the short-term

February 27, 2013

Rating Remains	**Buy**
Target price Remains	AUD 3.39
Closing price February 26, 2013	AUD 2.30
Potential upside	+47.4%

Action: 1H13 net loss less than expected

CUV's 1H13 net loss after tax was AUD4.8mn (vs. Nomura at AUD5.3mn). Differences compared to our forecasts include: 1) lower EPP revenue; and 2) higher R&D grant income.

Catalyst: CUV moving into Vitiligo market

CUV aims to show that its lead compound, afamelanotide, has efficacy against several sun-related diseases. CUV is investigating the efficacy of afamelanotide in Non-Segmental Vitiligo (NSV), a condition that affects up to 45mn people globally. In its Phase IIa NSV study, the primary study objective was achieved in that extent of repigmentation was significant in the treatment arm (p=0.025/p=0.023). From here, CUV will most likely undertake a Phase IIb trial likely to be conducted first in Europe and Asia.

Awaiting potential EU registration response for EPP

Submission of CUV's EU registration dossier for afamelanotide in EPP occurred on 6 February, 2012. The EMA timeline for arriving at a collective decision, and this decision being issued and published by the Committee for Human Medicinal Products (CHMP), normally is between 210 and 360 days after confirmation that a valid application has been received. We continue to await a decision from the EMA.

Valuation: TP AUD3.39 unchanged , Buy maintained

We have made no changes to our model assumptions in terms of the take-up of afamelanotide in its major markets, but have incorporated the 1H13 result. As a result, our TP is unchanged at AUD3.39ps.

30 Jun	FY12		FY13F		FY14F		FY15F
Currency (AUD)	Actual	Old	New	Old	New	Old	New
Revenue (mn)	1	4	4	8	8	21	21
Reported net profit (mn)	-10	-10	-9	-8	-8	0	0
Normalised net profit (mn)	-10	-10	-9	-8	-8	0	0
FD normalised EPS	-31.75c	-29.78c	-27.14c	-22.45c	-22.55c	0.07c	0.07c
FD norm. EPS growth (%)	na	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)	5.8	N/A	24.0	N/A	>100	N/A	>100
Dividend yield (%)	na	N/A	na	N/A	na	N/A	na
ROE (%)	-65.0	-121.8	-111.0	-457.7	-457.7	11.5	11.5
Net debt/equity (%)	net cash	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.

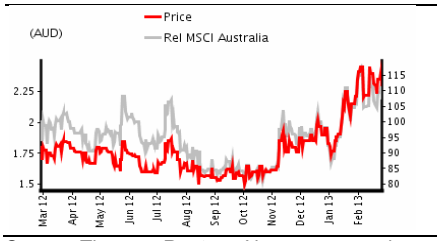
Key data on Clinuvel Pharmaceuticals

Income statement (AUDmn)

Year-end 30 Jun	FY11	FY12	FY13F	FY14F	FY15F
Revenue	**1**	**1**	**4**	**8**	**21**
Cost of goods sold	0	0	-1	-3	-8
Gross profit	**1**	**1**	**3**	**5**	**13**
SG&A	-14	-11	-13	-14	-14
Employee share expense					
Operating profit	**-13**	**-10**	**-10**	**-9**	**-1**
EBITDA	**-13**	**-10**	**-10**	**-9**	**-1**
Depreciation	0	0	0	0	0
Amortisation	0	0	0	0	0
EBIT	-13	-10	-10	-9	-1
Net interest expense	1	1	1	0	1
Associates & JCEs					
Other income	0	0	0	0	0
Earnings before tax	**-11**	**-10**	**-9**	**-8**	**0**
Income tax	0	0	0	0	0
Net profit after tax	**-11**	**-10**	**-9**	**-8**	**0**
Minority interests	0	0	0	0	0
Other items					
Preferred dividends					
Normalised NPAT	**-11**	**-10**	**-9**	**-8**	**0**
Extraordinary items	0	0	0	0	0
Reported NPAT	**-11**	**-10**	**-9**	**-8**	**0**
Dividends	0	0	0	0	0
Transfer to reserves	**-11**	**-10**	**-9**	**-8**	**0**
Valuation and ratio analysis					
Reported P/E (x)	na	na	na	na	>100
Normalised P/E (x)	-6.1	-7.2	-8.5	-10.2	3,158.6
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	4.4
Price/book (x)	4.3	5.8	24.0	>100	>100
EV/EBITDA (x)	na	na	na	na	na
EV/EBIT (x)	na	na	na	na	na
Gross margin (%)	100.0	100.0	68.4	63.7	62.6
EBITDA margin (%)	-1,205.8	-1,421.7	-220.7	-104.3	-4.3
EBIT margin (%)	-1,214.6	-1,430.3	-221.9	-105.1	-4.6
Net margin (%)	-1,096.0	-1,351.3	-209.6	-99.0	0.1
Effective tax rate (%)	na	na	na	na	30.0
Dividend payout (%)	na	na	na	na	0.0
Capex to sales (%)	6.7	0.6	2.5	1.4	0.6
Capex to depreciation (x)	0.8	0.1	2.0	2.0	2.0
ROE (%)	-53.3	-65.0	-111.0	-457.7	11.5
ROA (pretax %)	-139.9	-183.6	-177.6	-79.1	-4.2
Growth (%)					
Revenue	na	-30.6	520.9	82.3	157.8
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	-27.14c	-22.55c	0.07c
Norm EPS (AUD)	-37.58c	-31.75c	-27.14c	-22.55c	0.07c
Fully diluted norm EPS (AUD)	-37.58c	-31.75c	-27.14c	-22.55c	0.07c
Book value per share (AUD)	0.54	0.39	0.10	0.01	0.01
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)	7.0	27.8	26.4
Absolute (USD)	5.4	25.6	20.9
Relative to index	3.1	14.0	8.9
Market cap (USDmn)	84.9		
Estimated free float (%)	100.0		
52-week range (AUD)	2.46/1.5		
3-mth avg daily turnover (USDmn)	0.04		

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	-10	-9	-1
Change in working capital	3	3	5	6	19
Other operating cashflow	0	-3	0	0	1
Cashflow from operations	**-9**	**-10**	**-5**	**-2**	**19**
Capital expenditure	0	0	0	0	0
Free cashflow	**-10**	**-10**	**-5**	**-2**	**19**
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**	**19**
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**	**19**
Beginning cash	19	12	13	7	10
Ending cash	12	13	7	10	29
Ending net debt	-12	-13	-7	-10	-29

Source: Company data, Nomura estimates

Notes

CUV performed a capital raising in FY12

Balance sheet (AUDmn)

As at 30 Jun	FY11	FY12	FY13F	FY14F	FY15F
Cash & equivalents	12	13	7	10	29
Marketable securities	0	0	0	0	0
Accounts receivable	1	1	6	11	29
Inventories	0	0	0	0	0
Other current assets	7	2	2	2	2
Total current assets	**20**	**16**	**15**	**24**	**61**
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**	**15**	**24**	**61**
Short-term debt	0	0	0	0	0
Accounts payable	3	2	12	24	61
Other current liabilities	0	0	0	0	0
Total current liabilities	**4**	**2**	**12**	**24**	**61**
Long-term debt	0	0	0	0	0
Convertible debt					
Other LT liabilities	0	0	0	0	0
Total liabilities	**4**	**2**	**12**	**24**	**61**
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	-126
Proposed dividends					
Other equity and reserves	3	2	2	2	2
Total shareholders' equity	**16**	**14**	**3**	**0**	**0**
Total equity & liabilities	**20**	**16**	**15**	**24**	**61**
Liquidity (x)					
Current ratio	5.36	6.76	1.26	1.00	1.00
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	269.3	379.6	353.0
Days inventory	na	na	0.0	0.0	0.0
Days payable	na	na	1,760.6	2,161.8	1,947.6
Cash cycle	na	na	-1,491.3	-1,782.1	-1,594.6

Source: Company data, Nomura estimates

Notes

Cash and marketable securities at the end FY12 was AUD13mn

1H13 result

CUV's 1H13 net loss after tax was AUD4.8mn (vs. Nomura at AUD5.3mn). Differences compared to our forecasts include: 1) lower EPP revenue; and 2) higher R&D grant income.

We have made no changes to our model assumptions in terms of the take-up of afamelanotide in its major markets, but have incorporated the 1H13 result. Changes to our forecasts are shown below.

Fig. 1: CUV – changes to forecasts

	1H13A			FY13F			FY14F		
	Fcast	Actual	Diff (%)	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)
EBIT (AUDmn)	(5.7)	(5.1)	na	(10.8)	(10.9)	na	(8.4)	(8.6)	na
NPAT (AUDmn)	(5.3)	(4.8)	na	(10.2)	(10.3)	na	(7.9)	(8.1)	na
EPS (c)	(15.3)	(13.9)	na	(29.4)	(29.8)	na	(21.7)	(22.5)	na
DPS (c)	0.0	0.0	na	0.0	0.0	na	0.0	0.0	na
Net op cash flow (AUDmn)	(5.4)	(2.9)	na	(5.0)	(5.4)	na	(1.5)	(1.9)	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

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

1. CUV application for the treatment of EPP – awaiting a response

CUV believes that increases in skin melanin production through the application of afamelanotide will greatly improve EPP sufferers' total life quality by limiting the skin's light absorption.

EU application – MAA submission

CUV has already 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 alpha-melanocyte stimulating hormone, afamelanotide (16mg controlled-release formulation).

The primary objective of evaluating afamelanotide in EPP patients was to determine whether the prophylactic effect has meaningful clinical benefit. Afamelanotide treatment aims to allow patients to lead a life which includes exposing themselves to ambient light and to engage in outdoor activities. A similar, secondary objective was to assess the effect of treatment on their Quality of Life (QoL).The key results included:

- Patients receiving afamelanotide reported significantly less pain associated with phototoxicity (median pain score 6.0, p=0.035);
- Patients on active drug experienced half as many phototoxic reactions (p=0.044);
- Afamelanotide enabled patients to experience significantly more direct sunlight exposure without pain (p=0.005); and
- Patients on active drug reported a greater improvement in their Quality of Life (Day 270, p=0.011).

No safety concerns were identified during the study. Due to the results of this study, CUV submitted a Marketing Authorisation Application (MAA) for afamelanotide to the European Medicines Agency (EMA) in February 2012. Approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Lichtenstein. To date, four trials in EPP have been completed by the company.

Fig. 3: CUV's EPP clinical trial program

Trial	Phase	Patients enrolled	Study design (months duration)
CUV010	II (EU)	5	Provocation of symptoms by artifical light source (4)
CUV017	III (EU/AU)	101	Cross over study (12)
CUV029	III (EU)	77	2 Parallel arms placebo-active (9)
CUV030	II (US)	74	2 Parallel arms placebo-active (6)
	Total	257	

Source: Company data, Nomura research

Nomura comment

CUV has succeeded in enrolling an impressive number of patients into these 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.

Submission of CUV's EU registration dossier for afamelanotide occurred on 6 February, 2012. This dossier comprises all manufacturing aspects of the product, chemistry, as well as preclinical and clinical trial data.

The EMA timeline for arriving at a collective decision, and this decision being issued and published by the Committee for Human Medicinal Products (CHMP), normally is between 210 and 360 days after confirmation that a valid application has been received. We await a decision from the EMA.

2. Vitiligo – Phase IIa trial: primary endpoint reached

The primary endpoint was the extent of repigmentation between Day 0 and Day 168 as measured by the VASI and VETF scores (standard scoring methods for Vitiligo). The extent of repigmentation in the afamelanotide/NB-UVB group was significantly greater than observed in the NB-UVB-alone group (VASI, p=0.025; VETF p=0.023; 95% CI).

What are the VASI and VETF?

- The **Vitiligo Area Scoring Index** (VASI) recording system is a quantitative clinical tool that is used to evaluate Vitiligo and responses to treatment. Basically, the body is divided into five separate and mutually exclusive regions: hands, upper extremities (excluding hands), trunk, lower extremities (excluding the feet), and feet. At each follow-up assessment, any macular repigmentation is noted, and the extent of residual

depigmentation within each affected patch that had been present at baseline was estimated to the nearest of one of the following percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. The total body VASI is calculated by considering the contributions of all body regions.

- The **Vitiligo European Task Force** (VETF) recording system is a quantitative clinical tool that is used to evaluate Vitiligo and responses to treatment. Staging is based on cutaneous and hair pigmentation, and the disease is staged 0–4 on the largest macule in each body region, except hands and feet, which are assessed separately and globally as one unique area. Assessment of spreading is based on Wood's lamp examination of the same largest macule in each body area.

Apart from achieving its primary endpoint, here were a number of other interesting points to note from the trial result:

- **Treatment completion:** Forty-one (75.9%, n=41) patients completed the treatment. Thirteen patients withdrew due to their inability to comply with the demanding treatment protocol, or, in the case of five patients, due to the intensity of pigmentation experienced. Overall the combined treatment was well tolerated and no serious drug-related adverse events were reported;
- **May work better in those with darkest skin (i.e. those most affected by the cosmetic aspects of the disease):** As a subset analysis reflected by the VASI scores, significantly better, more complete and deeper repigmentation was observed for those patients with the darkest skin complexion (phototype IV-VI, n=24) who had received the combination therapy compared to in comparison to those on monotherapy (p=0.046; 95% CI).

What does it mean for CUV?

From here, CUV will undertake a Phase IIb trial likely to be conducted first in Europe and Asia. Starting from potential approval in 2016F, we believe that if an eventual 10% of US and EU patients were to use afamelanotide, the total CUV NSV opportunity is worth AUD7.73/share. At the current clinical stage, this translates to a risk-weighted NPV of AUD1.65/share from Vitiligo.

Result summary

We provide a summary of the interim result.

Fig. 4: CUV – result summary

Income statement (AUDmn)	1H12A	2H12A	2012A	1H13A	2H13F	2013F	1H13 on 1H12 (%)	2H13 on 2H12 (%)	FY13 on FY12 (%)
Sales revenue	0.0	0.7	0.7	0.5	3.5	4.0	nm	nm	nm
Other revenue	0.0	0.0	0.0	0.5	0.0	0.5	nm	nm	nm
Operating EBITDA	(6.6)	(3.6)	(10.3)	(5.1)	(5.7)	(10.8)	nm	nm	nm
Depreciation	0.0	(0.1)	(0.1)	0.0	(0.1)	(0.1)	nm	nm	nm
Amortisation	0.0	(0.0)	(0.0)	0.0	0.0	0.0	nm	nm	nm
Operating EBIT	(6.6)	(3.7)	(10.3)	(5.1)	(5.8)	(10.9)	nm	nm	nm
Net interest expense	0.3	0.2	0.6	0.2	0.3	0.6	nm	nm	nm
Pre-tax profit	(6.2)	(3.6)	(9.8)	(4.8)	(5.5)	(10.3)	nm	nm	nm
Tax	0.0	0.0	0.0	0.0	0.0	0.0	nm	nm	nm
Profit after tax	(6.2)	(3.6)	(9.8)	(4.8)	(5.5)	(10.3)	nm	nm	nm
Minorities	0.0	0.0	0.0	0.0	0.0	0.0	nm	nm	nm
Normalised NPAT	(6.2)	(3.6)	(9.8)	(4.8)	(5.5)	(10.3)	nm	nm	nm
Non-recurring items	0.0	0.0	0.0	0.0	0.0	0.0	nm	nm	nm
Reported NPAT	(6.2)	(3.6)	(9.8)	(4.8)	(5.5)	(10.3)	nm	nm	nm
Other information									
Normalised EPS (cps)	(20.3)	(11.6)	(31.8)	(13.9)	(15.9)	(29.8)	nm	nm	nm
DPS (cps)	0.0	0.0	0.0	0.0	0.0	0.0	nm	nm	nm
Average shares (mn)	30.6	30.8	30.8	34.7	34.7	34.7	nm	nm	nm

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 1H13A average rate, and recalculated interest income based on 1H13A cash balance and our FY13F forecast cash balance.

3. Valuation methodology and risks

Our updated risk-weighted valuation for EPP is unchanged at AUD3.39 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.

Fig. 5: 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	$1.74	90%	$1.93
Non-segmental Vitiligo	$1.65	21.4%	$7.73
Valuation	**$3.39**		$9.66

Source: Nomura estimates

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.

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.

Issuer Specific Regulatory Disclosures

The term "Nomura Group" used herein refers to Nomura Holdings, Inc. or any of its affiliates or subsidiaries, and may refer to one or more Nomura Group companies.

Materially mentioned issuers

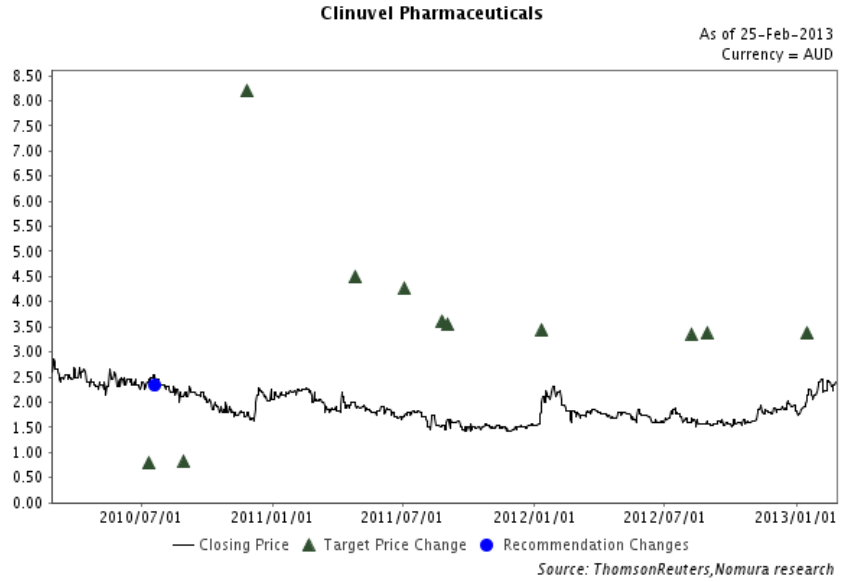
Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 2.30	26-Feb-2013	Buy	Not rated	A4,A5

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

A5 The Nomura Group has received compensation for investment banking services from the issuer in the past 12 months.

Clinuvel Pharmaceuticals (CUV AU) **AUD 2.30 (26-Feb-2013)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
16-Jan-13		3.39	2.15
29-Aug-12		3.38	1.63
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 AUD1.74/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 AUD1.65/share. Our risk-weighted valuation of the CUV pipeline (AUD3.39) 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.

Important Disclosures

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STOCKS

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