Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS



Erratum: Updating for capital raising & 4Q12

Funds to be used for further clinical development

August 8, 2012	
Rating Remains	Buy
Target price Reduced from 3.44	AUD 3.34
Closing price August 3, 2012	AUD 1.61
Potential upside	+107.5%

Action: CUV raises AUD6.0mn for further clinical development

CUV raised AUD6.0mn via a placement at a price of AUD1.75 per share. Management state that the funds raised in the placement will be used for: 1) a US Phase III clinical trial in erythropoietic protoporphyria (EPP); 2) a global clinical trial program in patients with Vitiligo; and 3) working capital during the evaluation of the Marketing Authorisation Application (MAA) for afamelanotide for the prophylactic treatment of adult patients with EPP by the European Medicine Agency (EMA). An approved MAA will allow Clinuvel to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Liechtenstein.

Catalyst: Advancing clinical trials in Non-Segmental Vitiligo (NSV)

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.

Valuation: TP AUD3.34 (from AUD3.44), Buy maintained

We have made no changes to our assumptions in terms of the take-up of afamelanotide in its major markets. We have updated our forecasts for the placement, Nomura's house foreign currency exchange rates and the release of CUV's 4Q12 cashflow statement. Our TP declines by 3.0% to AUD3.34. Buy maintained.

This note replaces an earlier published note which erroneously indicated the size of the capital raising. We apologise for any confusion this may have caused our readers.

30 Jun	FY11		FY12F		FY13F		FY14F
Currency (AUD)	Actual	Old	New	Old	New	Old	New
Revenue (mn)	1	1	1	4	4	8	8
Reported net profit (mn)	-11	-10	-10	-10	-10	-8	-8
Normalised net profit (mn)	-11	-10	-10	-10	-10	-8	-8
FD normalised EPS	-37.58c	-29.98c	-29.98c	-29.58c	-29.54c	-21.41c	-21.33c
FD norm. EPS growth (%)	na						
FD normalised P/E (x)	na	N/A	na	N/A	na	N/A	na
EV/EBITDA (x)	na						
Price/book (x)	3.0	N/A	4.4	N/A	23.0	N/A	na
Dividend yield (%)	na	N/A	na	N/A	na	N/A	na
ROE (%)	-53.3	-67.6	-67.1	-140.5	-135.8	-1,013.7	-757.8
Net debt/equity (%)	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 an excellent chance of CUV getting afamelanotide to 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)

Capex to depreciation (x)

ROE (%)

ROA (pretax %)

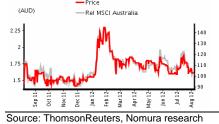
Growth (%)

Revenue

FRITDA

Income statement (AUDmn)					
Year-end 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
Revenue	0	1	1	4	8
Cost of goods sold	0	0	0	-2	-4
Gross profit	0	1	1	2	5
SG&A	-13	-14	-11	-13	-13
Employee share expense					
Operating profit	-13	-13	-10	-11	-8
EBITDA	-13	-13	-10	-11	-8
Depreciation	0	0	0	0	0
Amortisation	-1	0	0	0	0
EBIT	-13	-13	-10	-11	-8
Net interest expense	1	1	1	1	1
Associates & JCEs					
Other income	0	0	0	0	0
Earnings before tax	-12	-11	-10	-10	-8
Income tax	0	0	0	0	0
Net profit after tax	-12	-11	-10	-10	-8
Minority interests	0	0	0	0	0
Other items					
Preferred dividends					
Normalised NPAT	-12	-11	-10	-10	-8
Extraordinary items	0	0	0	0	0
Reported NPAT	-12	-11	-10	-10	-8
Dividends	0	0	0	0	0
Transfer to reserves	-12	-11	-10	-10	-8
Valuation and ratio analysis					
Reported P/E (x)	na	na	na	na	na
Normalised P/E (x)	-4.2	-4.3	-5.4	-5.5	-7.5
FD normalised P/E (x)	na	na	na	na	na
FD normalised P/E at price target (x)	na	na	na	na	na
Dividend yield (%)	na	na	na	na	na
Price/cashflow (x)	na	na	na	na	87.6
Price/book (x)	1.8	3.0	4.4	23.0	na
EV/EBITDA (x)	na	na	na	na	na
EV/EBIT (x)	na	na	na	na	na
Gross margin (%)	na	100.0	100.0	58.3	57.4
EBITDA margin (%)	na	-1,205.8	-1,186.5	-260.2	-99.4
EBIT margin (%)	na	-1,214.6	-1,196.5	-262.4	-100.5
Net margin (%)	na	-1,096.0	-1,127.2	-243.4	-92.1
Effective tax rate (%)	na	na	na	na	na
Dividend payout (%)	na	na	na	na	na
Capex to sales (%)	na	6.7	0.3	4.3	2.3
O	0.0	0.0	0.0	2.0	2.0

Relative performance chart (one year)



1M 3M 12M Absolute (AUD) -4.2 -10.1 7.3 Absolute (USD) -0.9 -6.3 8.6 Relative to index -7.7 -10.3 2.3 Market cap (USDmn) 62.1 Estimated free float (%) 100.0 52-week range (AUD) 2.31/1.4 3-mth avg daily turnover 0.03

Source: Thomson Reuters, Nomura research

Notes

Revenues started for CUV in FY11

LDITUA	IIa	11a	i ia	i ia	IIa
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)	-38.00c	-37.58c	-29.98c	-29.54c	-21.33c
Norm EPS (AUD)	-38.00c	-37.58c	-29.98c	-29.54c	-21.33c
Fully diluted norm EPS (AUD)	-38.00c	-37.58c	-29.98c	-29.54c	-21.33c
Book value per share (AUD)	0.87	0.54	0.37	0.07	-0.01
DPS (AUD)	0.00	0.00	0.00	0.00	0.00
Source: Company data, Nomura estimates					

0.6

-36.3

-89.1

na

0.8

na

-53.3

-139.9

0.0

-67.1

-189.4

-16.9

2.0

-135.8

-242.6

386.1

2.0

-757.8

-103.7

101.1

Cashflow (AUDmn)

Year-end 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
EBITDA	-13	-13	-10	-11	-8
Change in working capital	8	3	5	7	8
Other operating cashflow	-7	0	-4	1	1
Cashflow from operations	-12	-9	-10	-4	1
Capital expenditure	0	0	0	0	0
Free cashflow	-12	-10	-10	-4	0
Reduction in investments	0	0	0	0	0
Net acquisitions	10	3	5	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	-2	-7	-5	-4	0
Cash dividends	0	0	0	0	0
Equity issue	0	0	6	0	5
Debt issue	0	0	0	0	0
Convertible debt issue					
Others	0	0	0	0	0
Cashflow from financial acts	0	0	6	0	5
Net cashflow	-2	-7	1	-4	5
Beginning cash	22	19	12	13	9
Ending cash	19	12	13	9	15
Ending net debt	-19	-12	-13	-9	-15
Source: Company data, Nomura estimates					

Notes

CUV has performed a capital raising in FY12

Balance sheet (AUDmn)

Balance sheet (AUDmn)					
As at 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
Cash & equivalents	19	12	13	9	15
Marketable securities	0	0	0	0	0
Accounts receivable	0	1	1	4	8
Inventories	0	0	0	0	0
Other current assets	9	7	2	2	2
Total current assets	29	20	16	15	25
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	30	20	16	16	25
Short-term debt	0	0	0	0	0
Accounts payable	3	3	3	12	25
Other current liabilities	0	0	1	1	1
Total current liabilities	3	4	3	13	25
Long-term debt	0	0	0	0	0
Convertible debt					
Other LT liabilities	0	0	0	0	0
Total liabilities	3	4	3	13	26
Minority interest	0	0	0	0	0
Preferred stock	0	0	0	0	0
Common stock	113	113	119	119	124
Retained earnings	-89	-100	-110	-120	-128
Proposed dividends					
Other equity and reserves	2	3	3	3	3
Total shareholders' equity	26	16	13	2	0
Total equity & liabilities	30	20	16	16	25
Liquidity (x)					
Current ratio	9.59	5.36	4.66	1.17	0.97
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	na	234.3	377.1	205.8	255.6
Days inventory	na	234.3 na	na	0.0	0.0
		na	na	1,533.4	1,864.7
Dave navable	no				
Days payable Cash cycle	na na	na	na	-1,327.6	-1,609.1

Notes

Cash and marketable securities at the end 4Q12 was AUD13mn

CUV raises AUD6.0mn

CUV management believe this raising will lead to sufficient funds to enable the company to operate beyond the European EPP Marketing Authorisation Application (MAA) outcome, due anytime from mid-September 2012 to February 2013.

CUV raised AUD6.0mn via a placement. The placement was conducted at a price of AUD1.75 per share, representing a 4.3% premium to the 20-day volume-weighted average price and 9.4% to the closing price on June 20, 2012. We have made no changes to our model assumptions in terms of the take-up of afamelanotide in its major markets. We have updated our forecasts for the placement, Nomura's house foreign currency exchange rates and the release of CUV's 4Q12 cashflow statement. As a result, our target price declines by 3.0% to AUD3.34. Changes to our forecasts can be seen below.

Fig. 1: CUV - changes to forecasts

		FY12F		FY13F			FY14F		
	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)
EBIT (AUDmn)	(12.4)	(10.4)	na	(11.1)	(11.0)	na	(8.6)	(8.5)	na
NPAT (AUDmn)	(11.0)	(9.8)	na	(9.4)	(10.2)	na	(7.1)	(7.8)	na
EPS (c)	(30.2)	(30.0)	na	(22.6)	(29.5)	na	(16.9)	(21.3)	na
DPS (c)	0.0	0.0	na	0.0	0.0	na	0.0	0.0	na
Net op cash flow (AUDmn)	(11.8)	(10.0)	na	(8.5)	(3.6)	na	(2.3)	0.7	(129.7)

Source: 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 alphamelanocyte-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

	Wavelength		
Disorder	(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 AUD1.71/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.

Valuation

Our risk-weighted valuations for the near-term opportunities in the CUV pipeline are shown below. Given this analysis, we use our valuation of the CUV pipeline (i.e., AUD3.34) as our target price.

Fig. 3: 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	\$1.71	90%	\$1.89
Non-segmental Vitiligo	\$1.63	21.4%	\$7.62
Valuation	\$3.34		\$9.51

Source: Nomura estimates, Tufts data

Appendix A-1

Analyst Certification

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Issuer name	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 1.61	03-8-2012	Buy	Not rated	A4,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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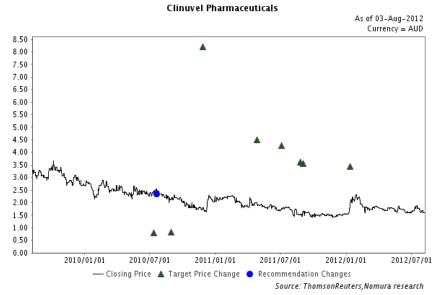
Previous Rating

Issuer name	Previous Rating	Date of change	
Clinuvel Pharmaceuticals	Not Rated	12-7-2010	

Clinuvel Pharmaceuticals (CUV AU)

Rating and target price chart (three year history)

AUD 1.61 (03-8-2012) Buy (Sector rating: Not rated)



Date	Rating	rarget price	Closing price
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\$1.71/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\$3.34) 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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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.

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SECTORS

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