Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

NOMURA
EQUITY RESEARCH

Updating for capital raising

Funds to be used for further clinical development

May 6, 2013

Rating Remains	**Buy**
Target price Reduced from 3.39	AUD 3.14
Closing price May 5, 2013	AUD 1.85
Potential upside	+69.7%

Raises AUD6.3mn for an expanded global clinical trial program

CUV has successfully raised AUD6.3mn via a private placement to international institutional and professional investors. The Placement was conducted at price of AUD2.136 per share, representing a 4.3% premium to the 20-day volume weighted average price on April 29 and 15.1% to the closing price on April 30.

CUV moving into Vitiligo market, awaiting EPP decision

The funds raised will be used by CUV for an expanded global clinical trial program with its drug afamelanotide 16mg implant in patients with the pigmentary disorder vitiligo. Funds will also be used to file a New Drug Application for afamelanotide 16mg implant with the US FDA, and to cover operating and commercialisation costs while the company awaits a delayed decision from the European Medicines Agency on its application for marketing authorisation (MAA) for the orphan indication erythropoietic protoporphyria (EPP). We believe the delay is likely to be due to the EMA's need to better understand this treatment for a rare patient population, and this delay is reasonably common in the cases of potential orphan drug approvals for rare diseases. We believe discussions from the EMA may occur in this case to demonstrate the potential importance of this drug to the relevant patient population. An EMA decision is anticipated in 2HCY13.

Valuation: TP AUD3.14 (from AUD3.39), 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. Our TP declines by 7.4% to AUD3.14. Buy maintained.

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	-9	-9	-8	-8	0	0
Normalised net profit (mn)	-10	-9	-9	-8	-8	0	0
FD normalised EPS	-31.75c	-27.14c	-25.63c	-22.55c	-20.01c	0.07c	0.61c
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)	4.7	N/A	7.1	N/A	10.7	N/A	10.3
Dividend yield (%)	na	N/A	na	N/A	na	N/A	na
ROE (%)	-65.0	-111.0	-79.1	-457.7	-93.1	11.5	3.5
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.

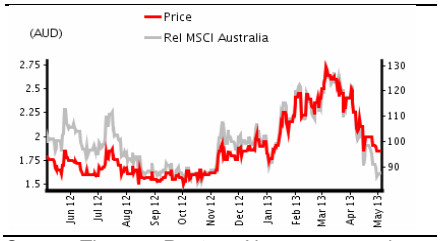
Key data on Clinuvel Pharmaceuticals

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	1	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)	-4.9	-5.8	-7.2	-9.2	301.3
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	3.8
Price/book (x)	3.4	4.7	7.1	10.7	10.3
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	-206.3	-95.3	1.2
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	-79.1	-93.1	3.5
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	-25.63c	-20.01c	0.61c
Norm EPS (AUD)	-37.58c	-31.75c	-25.63c	-20.01c	0.61c
Fully diluted norm EPS (AUD)	-37.58c	-31.75c	-25.63c	-20.01c	0.61c
Book value per share (AUD)	0.54	0.39	0.26	0.17	0.18
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)	-17.8	-24.5	3.4
Absolute (USD)	-18.4	-25.1	4.8
Relative to index	-23.0	-30.3	-14.8
Market cap (USDmn)	74.4		
Estimated free float (%)	100.0		
52-week range (AUD)	2.88/1.5		
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	1	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	6	5	0
Debt issue	0	0	0	0	0
Convertible debt issue					
Others	0	0	0	0	0
Cashflow from financial acts	**0**	**6**	**6**	**5**	**0**
Net cashflow	**-7**	**1**	**1**	**3**	**19**
Beginning cash	19	12	13	14	17
Ending cash	12	13	14	17	36
Ending net debt	-12	-13	-14	-17	-36

Source: Company data, Nomura estimates

Notes

CUV performed a capital raising in FY12 and FY13. We forecast a capital raising in FY14F

Balance sheet (AUDmn)

As at 30 Jun	FY11	FY12	FY13F	FY14F	FY15F
Cash & equivalents	12	13	14	17	36
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**	**21**	**30**	**68**
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**	**22**	**31**	**68**
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	126	131	131
Retained earnings	-100	-108	-118	-125	-125
Proposed dividends					
Other equity and reserves	3	2	2	2	2
Total shareholders' equity	**16**	**14**	**10**	**7**	**7**
Total equity & liabilities	**20**	**16**	**22**	**31**	**68**
Liquidity (x)					
Current ratio	5.36	6.76	1.80	1.28	1.11
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

Raises AUD6.3mn for an expanded global clinical trial program

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CUV moving into Vitiligo market

The funds raised will be used by CUV for an expanded global clinical trial program with its novel drug afamelanotide 16mg implant in patients with the pigmentary disorder vitiligo. Funds will also be used to file a New Drug Application for afamelanotide 16mg implant with the US FDA, and to cover operating and commercialisation costs while the company awaits a delayed decision from the European Medicines Agency on its application for marketing authorisation (MAA) for the orphan indication erythropoietic protoporphyria (EPP). An EMA decision is anticipated in 2H13.

Awaiting EPP application result

Clinuvel filed its MAA for afamelanotide 16mg implant on 6 February 2012 for the preventative treatment of the orphan light intolerance disorder erythropoietic protoporphyria (EPP). CUV recently announced that the European Medicines Agency (EMA) has allowed more time to complete the review of CUV's Marketing Authorisation Application (MAA) under the Centralised Procedure. The EMA procedure, led by the CHMP, has had at least a 10-week extension.

We believe the delay is likely to be due to the EMA's need to better understand this treatment for a rare patient population, and this delay is reasonably common in the cases of potential orphan drug approvals for rare diseases. We note that the EMA generally looks at: 1) manufacturing – CUV management previously reported that it had cleared its manufacturing audit in February 2013; and then 2) clinical and other – the clinical discussion is usually through the discussion of the disease treatment with medical Key Opinion Leaders and patient groups. We believe discussions from the EMA may occur in this case to demonstrate the potential importance of this drug to the relevant patient population.

Approval would allow CUV to market afamelanotide in all 27 European Union member states as well as Norway, Iceland and Lichtenstein. Changes to our forecasts can be seen below.

Fig. 1: CUV – changes to forecasts

	FY13F			FY14F			FY15F		
	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)
EBIT (AUDmn)	(10.9)	(10.9)	na	(8.6)	(8.6)	na	(1.0)	(1.0)	na
NPAT (AUDmn)	(10.3)	(10.2)	na	(8.1)	(7.8)	na	0.0	0.2	na
EPS (c)	(29.8)	(28.2)	na	(22.4)	(20.0)	na	0.1	0.6	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)	(5.2)	na	(1.9)	(1.6)	na	19.2	19.5	na

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 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

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 AUD7.13/share. At the current clinical stage, this translates to an updated risk-weighted NPV of AUD1.53/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 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 AUD1.61/share.

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., AUD3.14) as our target price.

Fig. 3: CUV – Valuation methodology

Valuation of CUV R&D portfolio	Risk-weighted valuation (A$ps)	Risk-weighting (in line with Clincial trial stage) (%)	Total opportunity (A$ps)
EPP	$1.61	90%	$1.79
Non-segmental Vitiligo	$1.53	21.4%	$7.13
Valuation	**$3.14**		$8.92

Source: Nomura estimates, Tufts data

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.

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Materially mentioned issuers

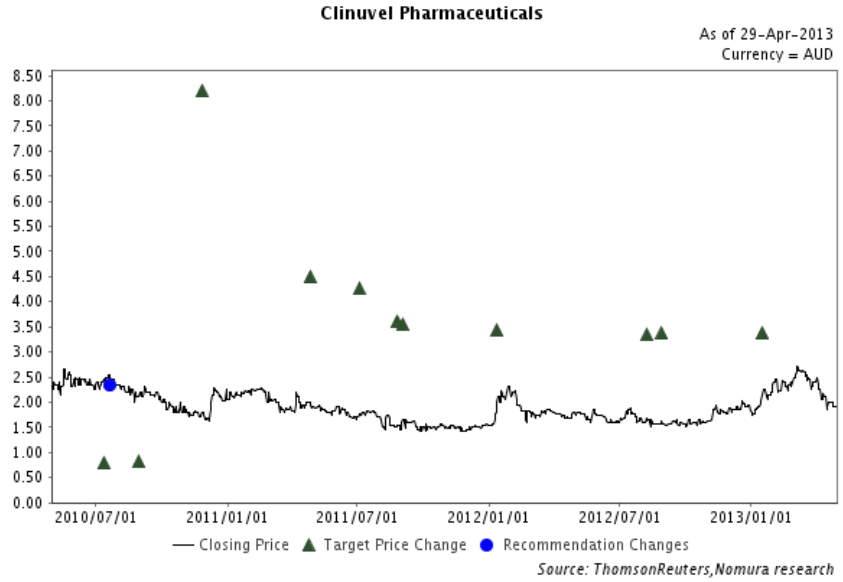
Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	AUD 1.85	30-4-2013	Buy	Not rated	A4,A5

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 1.85 (30-4-2013)** 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

Online availability of research and conflict-of-interest disclosures

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43% have been assigned a Buy rating which, for purposes of mandatory disclosures, are classified as a Buy rating; 40% of companies with this rating are investment banking clients of the Nomura Group*.
46% have been assigned a Neutral rating which, for purposes of mandatory disclosures, is classified as a Hold rating; 48% of companies with this rating are investment banking clients of the Nomura Group*.
11% have been assigned a Reduce rating which, for purposes of mandatory disclosures, are classified as a Sell rating; 23% of companies with this rating are investment banking clients of the Nomura Group*.
As at 31 March 2013. **The Nomura Group as defined in the Disclaimer section at the end of this report.*

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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

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