Clinuvel Pharmaceuticals CUV.AX CUV AU

HEALTH CARE & PHARMACEUTICALS

NOMURA
EQUITY RESEARCH

1H12 – a number of opportunities

We believe the Vitiligo market is currently underserved

February 27, 2012

Rating Remains	**Buy**
Target price Remains	AUD 3.44
Closing price February 24, 2012	AUD 1.82
Potential upside	+89%

Action: 1H12 loss greater than forecasts

CUV's 1H12 NPAT was -A$6.2mn (vs. Nomura at -A$5.3mn). We forecast CUV will undertake about A$20mn capital raising in FY12F in order to further fund its capital programme, particularly Vitiligo, based on our cashflow analysis.

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 to begin investigating the effectiveness of afamelanotide in Non-segmental Vitiligo, a condition that affects up to 45mn people globally. This is a different medical indication for afamelanotide. 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.

1H12 – positive Phase III for EPP

CUV 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 unchanged at A$3.44, Buy maintained

We make no changes to our model assumptions in terms of the take-up of afamelanotide in its major markets, but have revised future interest revenue in line with the 1H12 result. As a result, our target price is unchanged at A$3 44

30 Jun	FY11		FY12F		FY13F		FY14F
Currency (AUD)	Actual	Old	New	Old	New	Old	New
Revenue (mn)	1	2	2	4	4	8	8
Reported net profit (mn)	-11	-11	-11	-9	-9	-7	-7
Normalised net profit (mn)	-11	-11	-11	-9	-9	-7	-7
Normalised EPS	-37.58c	-29.59c	-30.47c	-22.34c	-22.56c	-17.39c	-17.44c
Norm. EPS growth (%)	na	na	na	na	na	na	na
Norm. P/E (x)	na	N/A	na	N/A	na	N/A	na
EV/EBITDA (x)	na	na	na	na	na	na	na
Price/book (x)	3.4	N/A	3.0	N/A	4.7	N/A	8.9
Dividend yield (%)	na	N/A	na	N/A	na	N/A	na
ROE (%)	-53.3	-50.5	-52.4	-44.1	-45.3	-57.2	-59.4
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 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.

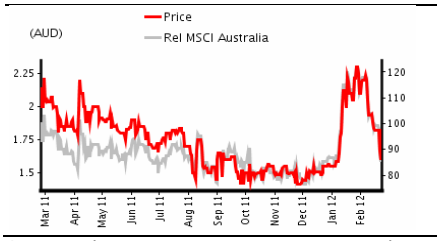
Key data on Clinuvel Pharmaceuticals

Income statement (AUDmn)

Year-end 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
Revenue	**0**	**1**	**2**	**4**	**8**
Cost of goods sold	0	0	-1	-1	-3
Gross profit	**0**	**1**	**1**	**3**	**5**
SG&A	-13	-14	-14	-13	-13
Employee share expense					
Operating profit	**-13**	**-13**	**-12**	**-11**	**-8**
EBITDA	**-13**	**-13**	**-12**	**-11**	**-8**
Depreciation	0	0	0	0	0
Amortisation	-1	0	0	0	0
EBIT	-13	-13	-12	-11	-8
Net interest expense	1	1	1	2	1
Associates & JCEs					
Other income	0	0	0	0	0
Earnings before tax	**-12**	**-11**	**-11**	**-9**	**-7**
Income tax	0	0	0	0	0
Net profit after tax	**-12**	**-11**	**-11**	**-9**	**-7**
Minority interests	0	0	0	0	0
Other items					
Preferred dividends					
Normalised NPAT	**-12**	**-11**	**-11**	**-9**	**-7**
Extraordinary items	0	0	0	0	0
Reported NPAT	**-12**	**-11**	**-11**	**-9**	**-7**
Dividends	0	0	0	0	0
Transfer to reserves	**-12**	**-11**	**-11**	**-9**	**-7**
Valuation and ratio analysis					
FD normalised P/E (x)	na	na	na	na	na
FD normalised P/E at price target (x)	na	na	na	na	na
Reported P/E (x)	na	na	na	na	na
Dividend yield (%)	na	na	na	na	na
Price/cashflow (x)	na	na	na	na	na
Price/book (x)	2.1	3.4	3.0	4.7	8.9
EV/EBITDA (x)	na	na	na	na	na
EV/EBIT (x)	na	na	na	na	na
Gross margin (%)	na	100.0	67.9	67.0	66.0
EBITDA margin (%)	na	-1,205.8	-610.0	-285.1	-108.5
EBIT margin (%)	na	-1,214.6	-614.3	-287.5	-109.7
Net margin (%)	na	-1,096.0	-545.1	-246.0	-95.3
Effective tax rate (%)	na	na	na	na	na
Dividend payout (%)	na	na	na	na	na
Capex to sales (%)	na	6.7	8.6	4.8	2.5
Capex to depreciation (x)	0.6	0.8	2.0	2.0	2.0
ROE (%)	-36.3	-53.3	-52.4	-45.3	-59.4
ROA (pretax %)	-89.1	-139.9	-169.2	-146.1	-81.8
Growth (%)					
Revenue	na	na	93.0	89.4	99.7
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)	-38.00c	-37.58c	-30.47c	-22.56c	-17.44c
Norm EPS (AUD)	-38.00c	-37.58c	-30.47c	-22.56c	-17.44c
Fully diluted norm EPS (AUD)	-38.00c	-37.58c	-30.47c	-22.56c	-17.44c
Book value per share (AUD)	0.87	0.54	0.61	0.38	0.20
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)	-17.6	29.1	-9.0
Absolute (USD)	-17.0	43.1	-3.4
Relative to index	-18.0	21.3	3.1
Market cap (USDmn)	70.3		
Estimated free float (%)	100.0		
52-week range (AUD)	2.31/1.4		
3-mth avg daily turnover (USDmn)	0.03		
Major shareholders (%)			
JM FG	6.9		

Source: Thomson Reuters, Nomura research

Notes

Revenues started for CUV in FY11

Cashflow (AUDmn)

Year-end 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
EBITDA	-13	-13	-12	-11	-8
Change in working capital	8	3	-2	1	2
Other operating cashflow	-7	0	1	1	1
Cashflow from operations	**-12**	**-9**	**-13**	**-9**	**-6**
Capital expenditure	0	0	0	0	0
Free cashflow	**-12**	**-10**	**-13**	**-9**	**-6**
Reduction in investments	0	0	0	0	0
Net acquisitions	10	3	2	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**	**-10**	**-9**	**-6**
Cash dividends	0	0	0	0	0
Equity issue	0	0	20	0	0
Debt issue	0	0	0	0	0
Convertible debt issue					
Others	0	0	0	0	0
Cashflow from financial acts	**0**	**0**	**20**	**0**	**0**
Net cashflow	**-2**	**-7**	**10**	**-9**	**-6**
Beginning cash	22	19	12	22	13
Ending cash	19	12	22	13	7
Ending net debt	-19	-12	-22	-13	-7

Source: Company data, Nomura estimates

Notes

We forecast a capital raising for CUV in FY12

Balance sheet (AUDmn)

As at 30 Jun	FY10	FY11	FY12F	FY13F	FY14F
Cash & equivalents	19	12	22	13	7
Marketable securities	0	0	0	0	0
Accounts receivable	0	1	2	4	7
Inventories	0	0	0	0	0
Other current assets	9	7	7	7	7
Total current assets	**29**	**20**	**31**	**23**	**21**
LT investments	0	0	0	0	0
Fixed assets	0	0	-2	-2	-2
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**	**28**	**21**	**19**
Short-term debt	0	0	0	0	0
Accounts payable	3	3	3	5	10
Other current liabilities	0	0	0	0	0
Total current liabilities	**3**	**4**	**3**	**5**	**11**
Long-term debt	0	0	0	0	0
Convertible debt					
Other LT liabilities	0	0	0	0	0
Total liabilities	**3**	**4**	**3**	**6**	**11**
Minority interest	0	0	0	0	0
Preferred stock	0	0	0	0	0
Common stock	113	113	133	133	133
Retained earnings	-89	-100	-111	-121	-128
Proposed dividends					
Other equity and reserves	2	3	3	3	3
Total shareholders' equity	**26**	**16**	**25**	**16**	**8**
Total equity & liabilities	**30**	**20**	**28**	**21**	**19**
Liquidity (x)					
Current ratio	9.59	5.36	10.08	4.27	1.97
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	259.8	260.8	256.2
Days inventory	na	na	0.0	0.0	0.0
Days payable	na	na	1,753.9	1,155.4	1,103.4
Cash cycle	na	na	-1,494.1	-894.6	-847.3

Source: Company data, Nomura estimates

Notes

Cash and marketable securities in FY11 was A$20mn

1HFY12 result

CUV posted 1H12 NPAT of -A$6.2mn, compared with our forecast of -A$5.3mn. We forecast CUV will undertake about A$20mn capital raising in FY12F in order to further fund its capital programme, particularly Vitiligo, based on our cashflow analysis.

We make no changes to our model assumptions in terms of the take-up of afamelanotide in its major markets, but have revised future interest revenue in line with the 1H FY12 results. Changes to our forecasts are shown below.

Fig. 1: CUV – changes to forecasts

		1H12A		FY12F			FY13F			FY14F		
	Fcast	Actual	Diff (%)	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)	Prev	Rev	Diff (%)
EBIT (AUDmn)	(6.1)	(6.6)	na	(12.4)	(12.4)	na	(11.1)	(11.1)	na	(8.6)	(8.6)	na
NPAT (AUDmn)	(5.3)	(6.2)	na	(10.7)	(11.0)	na	(9.4)	(9.5)	na	(7.5)	(7.5)	na
EPS (c)	(17.2)	(20.1)	na	(29.7)	(30.6)	na	(22.6)	(22.8)	na	(18.0)	(18.0)	na
DPS (c)	0.0	0.0	na	0.0	0.0	na	0.0	0.0	na	0.0	0.0	na
Net op cash flow (AUDmn)	(5.9)	(5.8)	na	(12.2)	(12.5)	na	(8.5)	(8.6)	na	(5.7)	(5.7)	na

Source: Company data, Nomura estimates

1. CUV recently announced positive results from pivotal European Phase III study

CUV 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).

CUV 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

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.

What is Erythropoietic protoporphyria (EPP)?

EPP is a rare and severe genetic disorder causing absolute UV and light intolerance in the skin. It occurs as a result of an enzyme deficiency that allows for an abnormal build-up of protoporphyrin, a molecule toxic to the body that transforms into excited states on absorption of light energy, causing photo-oxidative damage to the skin. This is manifested through various symptoms such as tingling, stinging, or burning and may accompany the appearance of a rash or blisters. Protoporphyrin build-up also causes general tissue nerve damage that can result in abdomen pain, stomach reflux or, in extreme cases, temporary psychosis. In dealing with the excess protoporphyrin, there is also a high potential for liver damage over time.

The photosensitive effects of EPP can be extremely painful and uncomfortable, often unbearably so. As such, the effect on a patient's lifestyle is normally dramatic. Most patients spend a considerable amount of time and effort avoiding excessive light sources and employing almost complete clothing coverage when possible. Since the photosensitivity results from light in the visual spectrum as well as UV, most sunscreens offer little protection, and severe cases may even struggle to find comfort indoors. Ultimately there is no cure for EPP, and limiting light exposure remains the best current treatment option.

Market opportunity for EPP

With no real treatment options for EPP sufferers beyond limiting light exposure, Clinuvel's afamelanotide therapy should prove efficacious. The disease is rare, affecting around one in 60,000-200,000 people worldwide, according to PubMed, although accurate statistics are hard to find. We estimate there are between 7,000 and 14,000 EPP sufferers across the US and Europe. Afamelanotide appears to be one of the few viable treatment options for EPP. CUV has received FDA Orphan drug designation (ODD), allowing for an accelerated review process and certain associated privileges.

What does it mean for CUV?

These are excellent clinical trial results, and should be seen positively by regulatory authorities. We note that CUV is already being reimbursed for its product for EPP in select EU countries, and hence the business model has already been substantially de-risked, in our view. We expect a MAA decision in the EU in 1HCY12.

2. First positive observations from Clinuvel's US vitiligo trial

CUV previously announced positive early clinical observations from the company's open-label Phase II pilot trial (CUV102) of the novel drug afamelanotide in patients with Non-segmental Vitiligo (NSV). NSV is a condition that affects up to 45mn people globally. Under the CUV102 protocol, 50% of the patients enrolled are undergoing repigmentation treatment with narrowband ultraviolet B (NB-UVB) therapy in combination with afamelanotide, while the remaining 50% are being treated with NB-UVB alone. The clinical objectives of the CUV102 trial are to determine whether afamelanotide reduces the total dose of radiation (NB-UVB) and the time required to reactivate skin pigment producing cells (melanocytes) in vitiliginous lesions.

Observations in 21 patients showed that monthly dosing of afamelanotide (16mg implant) in combination with NB-UVB has the capacity to achieve accelerated and deeper pigmentation of vitiliginous skin lesions.

Considerable savings for insurers in using CUV's product for NSV

NSV is a depigmenting disease that affects c10mn persons in the US and EU. We believe treatment of NSV with CUV's afamelanotide could provide an elegant solution to what is a disfiguring disease with a large unmet clinical need. We believe afamelanotide should act to decrease the time taken for a response to NB-UVB treatment, and hence be attractive on a pharmacoeconomic basis for public and private insurers. If afamelanotide halves NB-UVB treatment time, then the saving for insurers would be cUS$13,000 per treatment period. This is c37% of the current total cost of treatment of Vitiligo with NB-UVB.

CUV previously announced positive early clinical observations from the company's open-label Phase II pilot trial (CUV102) of the novel drug afamelanotide in patients with nonsegmental vitiligo (NSV)

CUV upside from potentially successful NSV trials

We have performed a scenario analysis of the potential NSV opportunity. 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 A$7.73/share. At the current clinical stage, this translates to a risk-weighted NPV of A$1.65/share from NSV.

3. Valuation methodology and risks

Our updated risk-weighted valuation for EPP is A$1.91/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. 2: 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	$1.78	90%	$1.98
Non-segmental Vitiligo	$1.65	21.4%	$7.73
Valuation	**$3.44**		$9.71

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 1.82	24-Feb-2012	Buy	Not rated	A6

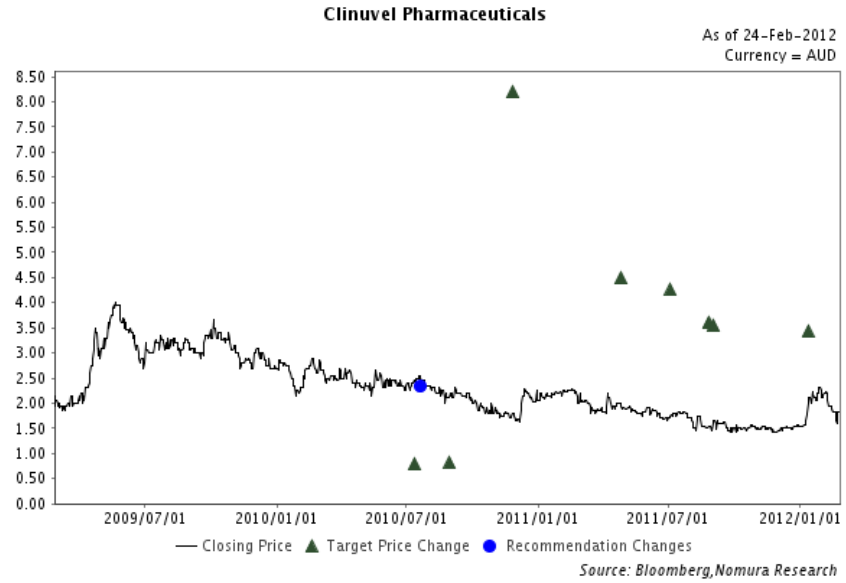
A6 A Nomura Group Company expects to receive or intends to seek compensation for investment banking services from the issuer in the next three months.

Previous Rating

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

Clinuvel Pharmaceuticals (CUV AU) **AUD 1.82 (24-Feb-2012)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target 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$1.78/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$1.65/share. Given the above analysis, we adopt our risk-weighted valuation of the CUV pipeline (A$3.44) as 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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6% have been assigned a Reduce rating which, for purposes of mandatory disclosures, are classified as a Sell rating; 0% of companies with this rating are investment banking clients of the Nomura Group*.
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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 (accessible through the left hand side of the Nomura Disclosure web page: http://go.nomuranow.com/research/globalresearchportal);**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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