Clinuvel Pharmaceuticals CUV AU

HEALTH CARE & PHARMACEUTICALS | AUSTRALIA

Maintained

BUY

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NOMURA
NOMURA AUSTRALIA LIMITED

Action

Clinuvel Pharmaceuticals (CUV) recently announced that it will investigate the effectiveness of its drug, afamelanotide, in non-segmental vitiligo, a condition that affects up to 45mn people globally. This is a new medical indication for afamelanotide, and has the potential to markedly increase the drug's addressable medical market, in our view. Maintain BUY.

Catalysts

Following the recent announcement of positive final results of a Phase III clinical trial in another disease, CUV will likely continue to seek EMEA marketing authorisation for afamelanotide, the final regulatory step before starting EU sales.

Anchor themes

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

Closing price on 25 Nov	A$1.73
Price target	**A$8.20**
	(from A$0.82)
Upside/downside	374.0%
Difference from consensus	**0.0%**
FY12F net profit (A$mn)	3.05
Difference from consensus	**-0.5%**

Source: Nomura

Nomura vs consensus

Our figures are the only numbers in consensus data.

Updating for share consolidation

② Clinuvel completes share consolidation

Clinuvel Pharmaceuticals (CUV) has completed a consolidation of company shares on a one-for-ten basis approved by shareholders at the 2010 Annual General Meeting on 10 November, 2010. Accordingly, we have updated our forecasts and price target to account for the share consolidation and the issuance of 1.35mn Conditional Performance Rights.

② Developing treatment for sun-related disease

CUV aims to show that its lead compound, afamelanotide, has efficacy against several sun-related diseases. This is an analogue of a hormone called alpha-melanocyte-stimulating hormone or alpha-MSH.

③ Statistically significant results in absolute sun allergy

Recently, CUV announced that it obtained positive results from a 12-month Phase III crossover study of afamelanotide as a photo-protectant for erythropoietic protoporphyria (EPP) or absolute sun allergy. The study showed that a significant reduction of the frequency of pain was observed in patients on the active drug [p=0.0023] and the assessment of all individual daily pain scores was significantly lower in patients receiving afamelanotide compared with those receiving the placebo [p=0.0017].

④ BUY maintained, PT at A$8.20 post share consolidation

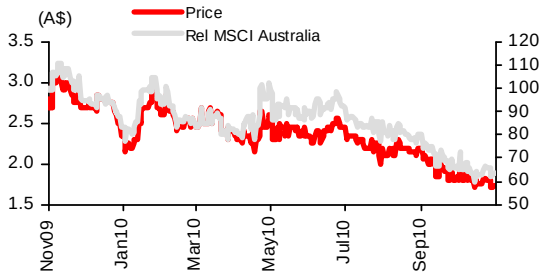
In FY11F, CUV is likely to receive the results of an EMEA marketing authorisation for afamelanotide for EPP, which is the final regulatory step before the start of EU sales. Marketing authorisation is usually granted three to nine months after filing in the US and EU.

Key financials & valuations

30 Jun (A$mn)	FY10	FY11F	FY12F	FY13F
Revenue	-	11.80	22.66	33.61
Reported net profit	(11.52)	(3.36)	3.05	9.04
Normalised net profit	(11.52)	(3.36)	3.05	9.04
Normalised EPS (A$)	(0.38)	(0.11)	0.10	0.30
Norm. EPS growth (%)	na	na	na	196.7
Norm. P/E (x)	na	na	17.2	5.8
EV/EBITDA (x)	na	na	12.8	1.9
Price/book (x)	2.0	2.3	2.0	1.5
Dividend yield (%)	0.0	0.0	0.0	0.0
ROE (%)	(36.3)	(13.6)	12.4	29.5
Net debt/equity (%)	net cash	net cash	net cash	net cash
Earnings revisions				
Previous norm. net profit		(3.36)	3.05	9.04
Change from previous (%)		0.0	(0.1)	0.1
Previous norm. EPS (A$)		1.11	1.01	2.98

Source: Company, Nomura estimates

Share price relative to MSCI Australia



	1m	3m	6m
Absolute (A$)	(6.5)	(21.4)	(33.5)
Absolute (US$)	(7.8)	(12.5)	(19.5)
Relative to Index	(3.7)	(30.1)	(48.7)

Market cap (US$mn)	51.5
Estimated free float (%)	100.0
52-week range (A$)	3.10/1.70
3-mth avg daily turnover (US$mn)	0.044
Stock borrowability	Hard
Major shareholders (%)	
JM FG	6.9

Source: Company, Nomura estimates

Any authors named on this report are research analysts unless otherwise indicated.
See the important disclosures and analyst certifications on pages 7 to 10.

Drilling down

What is afamelanotide?

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.

Recent results and timeline

Recently, CUV received the final results of its Phase III EPP trial and will now seek EMEA marketing authorisation for afamelanotide for EPP. This is the final regulatory step before the start of EU sales. Marketing authorisation is usually granted three to nine months after filing in the US and EU. CUV's timeline is shown below.

Exhibit 1. CUV: updated timeline for clinical trials and approvals

Date (CY)	Date (FY)	Trial	Nomura comment
13 July 2010		Release final results of EU/Australia Final Phase III EPP (CUV017)	EU regulatory review begins; likely to take three to nine months from filing date
End 4QCY10	End 2Q11	Complete Phase II EPP trial in US (CUV030)	Trial data should be released six months from completion
End 4QCY10	End 2Q11	Initiate Phase III SU trial in EU (CUV023)	Trial should be complete in four months
End 4QCY10	End 2Q11	Final results of EU Phase III PLE trial (CUV015)	Filing to be determined upon final results
4QCY10 to end 1QCY11	2Q11 to end 3Q11	Final results of Phase III SU trial in EU (CUV023)	Filing to be determined upon final results
4QCY10 to end 1QCY11	2Q11 to end 3Q11	EU regulatory approval — marketing authorisation EPP	Further EU revenue from EPP
4QCY10 to end 1QCY11	2Q11 to end 3Q11	US (FDA) regulatory filing for NDA — marketing authorisation EPP	Review time three to nine months (from filing date) – then start US revenue from EPP
4QCY10 to end 1QCY11	2Q11 to end 3Q11	Interim results for Phase II AK/SCC in OTR (CUV011)	CUV to evaluate results and determine whether to progress to Phase III

Note: as at August 2010

Source: Company data, Nomura estimates

The vitiligo opportunity

Vitiligo is a chronic pigmentation disorder in which melanocytes (the cells that make pigment) in the skin are destroyed. As a result, white patches appear on the skin in different parts of the body. Similar patches also appear on both the mucous membranes (tissues that line the inside of the mouth and nose), and the retina (inner layer of the eyeball). There are two types of Vitiligo – non-segmental (c85% of all cases), which tends to affect both sides of the body; and segmental (c15% of cases) which tends to affect one side of the body.

About 0.5-1.0% of the world's population, or as many as 65mn people have Vitiligo

CUV recently announced to the ASX that it will begin investigating the effectiveness of its melanocyte stimulating hormone, afamelanotide, in non-segmental vitiligo, a condition that affects up to 45mn people globally. This is a new medical indication for afamelanotide. MSB management plans to use afamelanotide as an adjunct to the current mainstay of treatment, narrow band UVB (NB-UVB), and test afamelanotide as a single-treatment option.

Scientific studies have shown that in non-segmental vitiligo there is a reduction in functional activity of melanocytes. It seems logical that doses of alpha-melanocyte stimulating hormone (afamelanotide) should stimulate under-functioning melanocytes and should increase the ability of the melanocytes to function under the action of NB-UVB therapy. In our view, the scientific basis for afamelanotide to have a role in the treatment of vitiligo seems reasonable.

It seems logical that doses of afamelanotide should stimulate under-functioning melanocytes and should increase the ability of the melanocytes to function under the action of NB-UVB therapy

In a large number of clinical trials afamelanotide has been shown to be safe. As well as the potential to increase the response to NB-UVB therapy, afamelanotide has the

potential to decrease the theoretical risk of skin damage and potential cancer from currently elevated doses of UV that are a necessary part of NB-UVB therapy.

In addition, we believe positive clinical trial results of afamelanotide should increase the perception of the medical necessity of afamelanotide. In turn, we believe this should be noted by regulatory authorities, who have yet to approve afamelanotide.

What does it mean for CUV?

We believe that there is no single treatment for the disease. Hence, should clinical trials be positive, there is potential for afamelanotide to be a viable option for treatment of the disease. We have performed a scenario analysis on the potential opportunity for CUV. We believe that if 10% of US and EU patients were to use afamelanotide from 2014 onwards, the risk-weighted NPV for the vitiligo opportunity alone for CUV would be A$10.33/share. This is seen below.

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Exhibit 2. CUV: risk-weighted NPV for vitiligo opportunity

Number of US and EU patients with Vitiligo (mn)	**3**
Assume 10% of patients treated in 2014 (mn)	0.3
Number of implants per person (pa)	4
Hence, number of implants per year (mn)	1.2
Cost of implant (US$) in 2014	1,000
Hence, size of potential market (US$ mn)	1,200
Assumed growth of market pa (%)	2
Assuming NPAT margin of 25%, NPV to 2025 (A$ per share)	51.64
20% risk-weighted NPV (A$ per share)	**10.33**

Source: PubMed, Nomura estimates

We have made a number of assumptions in developing this analysis. These include:

- **Costs to develop this opportunity.** We assume that it will cost CUV A$50mn to progress this opportunity to the end of Phase III clinical trials, spent progressively from FY11F to FY13F. We have not assumed a CUV capital raising, and that CUV will have sufficient cash to complete this opportunity;
- **Cash flow from the opportunity.** We assume that capex equals depreciation for the life of the project, and hence, cashflow is equivalent to NPAT. We assume the project will end in 2025 (in line with the run off in CUV's patents) and has no terminal value;
- **Growth of the market.** We assume that the addressable market will expand by 2% pa;
- **A$/US$ exchange rate.** We assume an A$/US$ exchange rate of 0.7 for the life of the project;
- **Discount rate.** We use our assumed WACC of 14.3% for CUV to determine the discount rate for the project;
- **Number of shares.** We use the current number of CUV shares to determine NPV per share; and
- **Risk weighting of the opportunity.** On an industry-wide basis, we believe the chances of getting a product to market from the Phase II stage are 20-30%. Hence, we have 20% risk-weighted the potential opportunity.

Investment case

We highlight our investment case for CUV below.

CUV's trials are relatively advanced

CUV has two trials in Phase III. On an industry-wide basis, the success rate in getting a product to market from the Phase III stage is in the order of 70%. As such, we believe that there is a good chance of CUV getting afamelanotide to market. This points to cashflow from sales, and sooner than for most other biotechnology companies, in our view.

We believe that there is a good chance of CUV getting afamelanotide to market

Free potential upside from other clinical trials

In developing our valuation for CUV, we have not included any valuation of CUV's development of a product to treat other sun-related disorders. CUV's afamelanotide has been shown to result in significant improvement in several sun-related disorders.

High cash levels

CUV has a net cash (including marketable securities) position of A$29.2mn. We see potentially valuable opportunities, and given current cash levels, we think it is unlikely that CUV will need to raise equity to progress its trials.

Valuation methodology and risks

On a DCF analysis, we derive a price target for CUV assuming a WACC of 14.25%. We factor in an initial selling price of €1,500 per implant and assume that this will decline by 2% pa. In line with most pharmaceutical companies, we expect CUV to achieve a steady-state gross profit margin of 70%.

Risks to our investment view

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

Financial statements

Income statement (A$mn)					
Year-end 30 Jun	**FY09**	**FY10**	**FY11F**	**FY12F**	**FY13F**
Revenue	-	-	11.8	22.7	33.6
Cost of goods sold	-	-	(3.5)	(6.8)	(10.1)
Gross profit	**-**	**-**	**8.3**	**15.9**	**23.5**
SG&A	(18.3)	(13.4)	(13.6)	(13.5)	(13.2)
Employee share expense					
Operating profit	**(18.3)**	**(13.4)**	**(5.3)**	**2.3**	**10.3**
EBITDA	**(17.4)**	**(12.7)**	**(5.2)**	**2.4**	**10.4**
Depreciation	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Amortisation	(0.8)	(0.6)	-	-	-
EBIT	**(18.3)**	**(13.4)**	**(5.3)**	**2.3**	**10.3**
Net interest expense	2.7	1.5	1.9	2.0	2.6
Associates & JCEs					
Other income	0.2	0.4	-	-	-
Earnings before tax	**(15.4)**	**(11.5)**	**(3.4)**	**4.4**	**12.9**
Income tax	-	-	-	(1.3)	(3.9)
Net profit after tax	**(15.4)**	**(11.5)**	**(3.4)**	**3.0**	**9.0**
Minority interests	-	-	-	-	-
Other items					
Preferred dividends					
Normalised NPAT	**(15.4)**	**(11.5)**	**(3.4)**	**3.0**	**9.0**
Extraordinary items	-	-	-	-	-
Reported NPAT	**(15.4)**	**(11.5)**	**(3.4)**	**3.0**	**9.0**
Dividends	-	-	-	-	-
Transfer to reserves	**(15.4)**	**(11.5)**	**(3.4)**	**3.0**	**9.0**
Valuation and ratio analysis					
FD normalised P/E (x)	na	na	na	17.2	5.8
FD normalised P/E at price target (x)	na	na	na	81.6	27.5
Reported P/E (x)	na	na	na	17.2	5.8
Dividend yield (%)	-	-	-	-	-
Price/cashflow (x)	na	na	na	9.4	4.5
Price/book (x)	1.4	2.0	2.3	2.0	1.5
EV/EBITDA (x)	na	na	na	12.8	1.9
EV/EBIT (x)	na	na	na	13.3	1.9
Gross margin (%)	na	na	70.0	70.0	70.0
EBITDA margin (%)	na	na	(44.3)	10.7	30.9
EBIT margin (%)	na	na	(45.0)	10.3	30.6
Net margin (%)	na	na	(28.5)	13.5	26.9
Effective tax rate (%)	na	na	na	30.0	30.0
Dividend payout (%)	na	na	na	-	-
Capex to sales (%)	na	na	1.4	0.8	0.6
Capex to depreciation (x)	0.4	0.6	2.0	2.0	2.0
ROE (%)	(34.6)	(36.3)	(13.6)	12.4	29.5
ROA (pretax %)	(74.4)	(89.1)	(52.3)	22.3	94.4
Growth (%)					
Revenue	na	na	na	92.1	48.3
EBITDA	na	na	na	na	329.9
EBIT	na	na	na	na	342.3
Normalised EPS	na	na	na	na	196.7
Normalised FDEPS	na	na	na	na	196.7
Per share					
Reported EPS (A$)	(0.51)	(0.38)	(0.11)	0.10	0.30
Norm EPS (A$)	(0.51)	(0.38)	(0.11)	0.10	0.30
Fully diluted norm EPS (A$)	(0.51)	(0.38)	(0.11)	0.10	0.30
Book value per share (A$)	1.22	0.87	0.76	0.86	1.16
DPS (A$)	-	-	-	-	-

Source: Nomura estimates

We forecast revenues for CUV from FY11F

Cashflow (A$mn)					
Year-end 30 Jun	**FY09**	**FY10**	**FY11F**	**FY12F**	**FY13F**
EBITDA	(17.4)	(12.7)	(5.2)	2.4	10.4
Change in working capital	9.9	7.6	0.2	2.5	2.5
Other operating cashflow	(3.4)	(6.8)	1.9	0.7	(1.2)
Cashflow from operations	**(11.0)**	**(11.8)**	**(3.0)**	**5.6**	**11.6**
Capital expenditure	(0.0)	(0.0)	(0.2)	(0.2)	(0.2)
Free cashflow	**(11.0)**	**(11.8)**	**(3.2)**	**5.4**	**11.4**
Reduction in investments	-	-	-	-	-
Net acquisitions	-	9.7	-	-	-
Reduction in other LT assets	-	-	-	-	-
Addition in other LT liabilities	0.0	0.0	-	-	-
Adjustments	(0.0)	(0.0)	-	-	-
Cashflow after investing acts	**(11.0)**	**(2.1)**	**(3.2)**	**5.4**	**11.4**
Cash dividends	-	-	-	-	-
Equity issue	0.1	-	-	-	-
Debt issue	-	-	-	-	-
Convertible debt issue					
Others	6.8	(0.2)	-	-	-
Cashflow from financial acts	**7.0**	**(0.2)**	**-**	**-**	**-**
Net cashflow	**(4.0)**	**(2.3)**	**(3.2)**	**5.4**	**11.4**
Beginning cash	25.8	21.7	19.4	16.2	21.6
Ending cash	21.7	19.4	16.2	21.6	33.1
Ending net debt	(21.7)	(19.4)	(16.2)	(21.6)	(33.1)

Source: Nomura estimates

Balance sheet (A$mn)					
As at 30 Jun	**FY09**	**FY10**	**FY11F**	**FY12F**	**FY13F**
Cash & equivalents	21.7	19.4	16.2	21.6	33.1
Marketable securities					
Accounts receivable	0.2	0.4	0.4	0.8	1.1
Inventories	-	-	-	-	-
Other current assets	18.7	9.4	9.4	9.4	9.4
Total current assets	**40.6**	**29.2**	**26.0**	**31.8**	**43.6**
LT investments	-	-	-	-	-
Fixed assets	0.4	0.3	0.4	0.5	0.6
Goodwill	-	-	-	-	-
Other intangible assets	0.7	0.0	0.0	0.0	0.0
Other LT assets	-	-	-	-	-
Total assets	**41.6**	**29.5**	**26.4**	**32.3**	**44.2**
Short-term debt	-	-	-	-	-
Accounts payable	4.4	2.8	3.1	5.9	8.8
Other current liabilities	0.2	0.2	0.2	0.2	0.2
Total current liabilities	**4.5**	**3.0**	**3.3**	**6.2**	**9.0**
Long-term debt	-	-	-	-	-
Convertible debt					
Other LT liabilities	0.0	0.0	0.0	0.0	0.0
Total liabilities	**4.6**	**3.1**	**3.4**	**6.2**	**9.1**
Minority interest	-	-	-	-	-
Preferred stock	-	-	-	-	-
Common stock	113.2	113.2	113.2	113.2	113.2
Retained earnings	(78.3)	(89.0)	(92.3)	(89.3)	(80.2)
Proposed dividends					
Other equity and reserves	2.2	2.2	2.2	2.2	2.2
Total shareholders' equity	**37.1**	**26.4**	**23.1**	**26.1**	**35.2**
Total equity & liabilities	**41.6**	**29.5**	**26.4**	**32.3**	**44.2**
Liquidity (x)					
Current ratio	8.93	9.59	7.83	5.16	4.83
Interest cover	na	na	na	na	na
Leverage					
Net debt/EBITDA (x)	na	na	na	net cash	net cash
Net debt/equity (%)	net cash	net cash	net cash	net cash	net cash
Activity (days)					
Days receivable	na	na	11.8	9.4	10.3
Days inventory	na	na	-	-	-
Days payable	na	na	303.5	242.4	266.2
Cash cycle	na	na	(291.7)	(233.0)	(255.8)

Source: Nomura estimates

We believe CUV's cash burn will increase as trials continue

Any Authors named on this report are Research Analysts unless otherwise indicated

ANALYST CERTIFICATIONS

We, David Stanton and Zara Lyons, hereby certify (1) that the views expressed in this Research report accurately reflect our personal views about any or all of the subject securities or issuers referred to in this Research report, (2) no part of our 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 our 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	Ticker	Price (as at last close)	Closing Price Date	Rating	Disclosures
Clinuvel Pharmaceuticals	CUV AU	0.18 AUD	11 Nov 2010	Buy	

Previous Ratings

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

Three-year stock price and rating history

Not Available for Clinuvel Pharmaceuticals

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Explanation of Nomura's equity research rating system for Asian companies under coverage ex Japan published from 30 October 2008 and in Japan from 6 January 2009

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Explanation of Nomura's equity research rating system in Japan published prior to 6 January 2009 (and ratings in Europe, Middle East and Africa, US and Latin America published prior to 27 October 2008)

STOCKS
A rating of '1' or '**Strong buy'**, indicates that the analyst expects the stock to outperform the Benchmark by 15% or more over the next six months.
A rating of '2' or '**Buy'**, indicates that the analyst expects the stock to outperform the Benchmark by 5% or more but less than 15% over the next six months.
A rating of '3' or '**Neutral'**, indicates that the analyst expects the stock to either outperform or underperform the Benchmark by less than 5% over the next six months.
A rating of '4' or '**Reduce'**, indicates that the analyst expects the stock to underperform the Benchmark by 5% or more but less than 15% over the next six months.
A rating of '5' or '**Sell'**, indicates that the analyst expects the stock to underperform the Benchmark by 15% or more over the next six months.
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SECTORS
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A '**Bearish'** stance, indicates that the analyst expects the sector to underperform the Benchmark during the next six months.
Benchmarks are as follows: **Japan**: TOPIX; **United States**: S&P 500, MSCI World Technology Hardware & Equipment; **Europe**, by sector - *Hardware/Semiconductors*: FTSE W Europe IT Hardware; *Telecoms*: FTSE W Europe Business Services; *Business Services*: FTSE W Europe; *Auto & Components*: FTSE W Europe Auto & Parts; *Communications equipment*: FTSE W Europe IT Hardware; **Ecology Focus**: Bloomberg World Energy Alternate Sources; **Global Emerging Markets**: MSCI Emerging Markets ex-Asia.

Explanation of Nomura's equity research rating system for Asian companies under coverage ex Japan published prior to 30 October 2008

STOCKS

Stock recommendations are based on absolute valuation upside (downside), which is 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. However, if the analyst doesn't think the market will revalue the stock over the specified time horizon due to a lack of events or catalysts, then the fair value may differ from the intrinsic fair value. In most cases, therefore, our recommendation is an assessment of the difference between current market price and our estimate of current intrinsic fair value. Recommendations are set with a 6-12 month horizon unless specified otherwise. Accordingly, within this horizon, price volatility may cause the actual upside or downside based on the prevailing market price to differ from the upside or downside implied by the recommendation.
A '**Strong buy**' recommendation indicates that upside is more than 20%.
A '**Buy**' recommendation indicates that upside is between 10% and 20%.
A '**Neutral**' recommendation indicates that upside or downside is less than 10%.
A '**Reduce**' recommendation indicates that downside is between 10% and 20%.
A '**Sell**' recommendation indicates that downside is more than 20%.

SECTORS
A '**Bullish**' rating means most stocks in the sector have (or the weighted average recommendation of the stocks under coverage is) a positive absolute recommendation.
A '**Neutral**' rating means most stocks in the sector have (or the weighted average recommendation of the stocks under coverage is) a neutral absolute recommendation.
A '**Bearish**' rating means most stocks in the sector have (or the weighted average recommendation of the stocks under coverage is) a negative absolute recommendation.

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