ABN·AMRO

Thursday 31 January 2008

Clinuvel Pharmaceuticals

Fully committed

CUV has affirmed its commitment to commercialising CUV1647 in two years. As at 31 December 2007, CUV had cash reserves of A$56.9m, which is in line with our forecasts. This compares to its current market capitalisation of about A$109m. Buy.

Key forecasts

	FY06A	FY07A	FY08F	FY09F	FY10F
EBITDA (A$m)	-10.3	-10.6	-14.4	-12.3	-2.49
Reported net profit (A$m)	-10.8	-9.18	-13.6	-12.2	-2.91
Normalised net profit (A$m)[1]	-10.8	-9.18	-13.6	-12.2	-2.91
Normalised EPS (c)[1]	-6.87	-3.70	-4.52	-4.05	-0.96
Normalised EPS growth (%)	-42.9	-46.2	22.2	-10.3	-76.2
Dividend per share (c)	0.00	0.00	0.00	0.00	0.00
Dividend yield (%)	0.00	0.00	0.00	0.00	0.00
Normalised PE (x)	n/m	n/m	n/m	n/m	n/m
EV/EBITDA (x)	n/m	n/m	n/m	n/m	n/m
Price/net oper. CF (x)	-4.81	-10.6	-8.55	-9.76	-77.8
ROIC (%)	-291.7	-148.4	-33.9	-30.1	-8.13

1. Pre-goodwill amortisation and exceptional items ***year to Jun, fully diluted***
Accounting Standard: IFRS
Source: Company data, ABN AMRO forecasts

CUV affirms commitment to commercialising CUV1647

CUV has affirmed its commitment to commercialising CUV1647 inside two years. In 2007, CUV advanced clinical testing of CUV1647 against three skin disorders: Polymorphic Light Eruption (PLE or sun poisoning), Erythropoietic Protoporphyria (EPP or absolute sun intolerance) and Actinic Keratosis and Squamous Cell Carcinoma (AK/SCC) in organ transplant patients. In 2008, CUV will also be testing efficacy against Solar Urticaria (SU or anaphylactic reaction to the sun) and Photodynamic Therapy (PDT or photosensitivity associated with cancer treatment). The trial is expected to take two years, and its timing is in line with our forecasts.

Quarterly update - status quo

In its 2QFY08 report, CUV announced net operating cash flow after interest and tax was -A$1.80m for 2QFY08. This compares favourably to our FY08F forecast of -A$12.4m, demonstrating slower-than-expected cash burn in 2Q08. We believe the rate of cash burn will increase as the company further enters Phase III trials. As at end 2007, CUV had cash reserves of A$56.9m to fund its development plans for CUV1647. In addition, management said that it believes it will "have no further funding requirement". This compares to its current market capitalisation of about A$109m. Therefore the implied value of its clinical progress, patents and potential future cash flow is less than A$50m.

Our valuation and 12-month target price for CUV remains at A$1.15

We have not changed our forecasts after the quarterly update. CUV has two Phase III trials for PLE and EPP, with interim results expected in 2HCY08. It also has three Phase II trials for SU, PDT and AK/SCC. Given the near-term potential cash flow, we believe this warrants a premium compared to many other biotechnology companies. Finally, after the successful completion of the restructuring of the funds of one of the major shareholders, which had been a perceived overhang in the stock, we believe the situation is now far more stable than previously.

Important disclosures can be found in the Disclosures Appendix.
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ABN AMRO Equities Australia Ltd, ABN 84 002 768 701, AFS Licence 240530
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Produced by: ABN AMRO Equities Australia Ltd

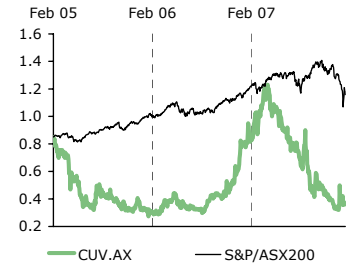
Buy

Absolute performance
n/a
Short term (0-60 days)

Pharmaceuticals & Biotechnology
Australia

Price
A$0.355
Target price
A$1.15
Market capitalisation
A$105.75m (US$94.00m)
Avg (12mth) daily turnover
A$0.40m (US$0.34m)
Reuters CUV.AX **Bloomberg** CUV AU

Price performance	(1M)	(3M)	(12M)
Price (A$)	0.3	0.5	0.9
Absolute %	2.9	-24.5	-62.6
Rel market %	16.1	-9.3	-61.3
Rel sector %	2.9	-22.5	-61.4



Stock borrowing: Easy onshore, Impossible offshore
Volatility (30-day): 136.64%
Volatility (6-month trend): ↑
52-week range: 1.40-0.31
S&P/ASX200: 5618.70
BBG AP Pharm & Biotech: 156.11

Source: ABN AMRO, Bloomberg

Analysts

Dr David Stanton

Zara Lyons

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CUV affirms commitment to commercialisation of CUV1647

The main opportunity for Clinuvel (CUV) is in the development of a treatment against polymorphous light eruption. This treatment is known as CUV1647, and is administered via an injection, under the skin, of a slow-release deposit of CUV1647, with the majority of the release occurring over the first 5-10 days. CUV1647 is a synthetic analogue of alpha-melanocyte-stimulating hormone (alpha-MSH) that is usually secreted by skin cells known as keratinocytes.

In 2007, CUV advanced clinical testing of CUV1647 against three skin disorders: Polymorphic Light Eruption (PLE or sun poisoning), Erythropoietic Protoporphyria (EPP or absolute sun intolerance) and Actinic Keratosis and Squamous Cell Carcinoma (AK/SCC) in organ transplant patients. Fair-skinned patients who have received organ transplants are 65-100x more likely to subsequently contract skin cancers because of the side effects of critical life-long administration of immune suppressive drugs. The trial will evaluate the drug's ability to reduce the incidence of AK and irreversible skin damage in immune compromised organ-transplant patients.

In 2008, CUV will also be testing efficacy against Solar Urticaria (SU or anaphylactic reaction to the sun) and Photodynamic Therapy (PDT or photosensitivity associated with cancer treatment). Its clinical trial program consists of: Phase III trials of EPP and PLE. In addition to Phase II trials of SU, PDT and AK/SCC.

CUV has affirmed its commitment to commercialising CUV1647 inside two years. Based on its clinical trial program to date and research, management is "confident that CUV1647 will eventually prove to be a highly attractive and competitive prophylactic treatment for UV and light-related skin disorders".

As at 31 December 2007, CUV had cash reserves of A$56.9m to fund its development plans for CUV1647. In an open briefing on 22 December 2007, management said that it believes it will "have no further funding requirement". This compares to its current market capitalisation of about A$109m. Therefore the implied value of its clinical progress, patents and potential future cash flow is currently less than A$50m.

Meanwhile CUV has announced that it expects to file an IND application (Investigational New Drug) with the US FDA in the next few weeks.

A number of opportunities for CUV

CUV is progressing five opportunities for its CUV1647 product through Phase II and III clinical trials:

- **PMLE** – CUV started its Phase III clinical trials of CUV1647 against polymorphous light eruption (PMLE) in May 2007, and should report the results of these towards the start of 2HCY08. PMLE is an acquired disease and is the most common of the disease reactions to sunlight that have an unknown cause. PMLE is characterised by recurrent, abnormal, delayed reactions to sunlight, consisting of a number of different types of lesions on sunlight-exposed surfaces. Within any one patient, only one clinical type of lesion is consistently manifested.
- **EPP** – On 5 June 2007, Clinuvel announced the Phase III trial of CUV1647 in erythropoietic protoporphyria (EPP) had begun in Zurich, Switzerland. This Phase III multicentre study is designed to determine whether CUV1647 can reduce the number and severity of phototoxic reactions in patients with EPP. In addition, the trial will determine whether CUV1647 can increase the duration of exposure to sunlight that can be tolerated by EPP patients. The company anticipates that 50-

70 EPP patients will participate in the trial with patients undergoing 12 months of treatment. The interim results are expected in mid-CY08. Applications to obtain ethics and regulatory approval are currently being prepared and submitted in a number of other trial sites across Europe and Australia. Additionally, the first Australian Phase III EPP trial is scheduled to start in the second half of 2007.

- **Skin cancer trial for organ transplant patients** – CUV is progressing a Phase II trial for those with squamous cell carcinoma (SCC) and actinic keratosis (AK), a precursor to skin cancers. Organ transplant patients with fair skin are 65-100 times more likely to develop skin cancer on prescribed immune-suppressant medication following their transplant compared to the general population. CUV is progressing a trial to see if CUV1647 is a treatment option to prevent cancers in this population. If successful, it is likely clinical trials will be initiated to determine whether CUV1647 is effective against these cancers in the general population.
- **Solar urticaria** – Solar urticaria is a rare disease characterised by itching, stinging, erythema and wheal formation after a brief period of exposure to natural sunlight or an artificial light source emitting the appropriate wavelength. CUV has started its Phase II clinical trials of CUV1647 against this disease, and should report the results of these clinical trials toward the start of 2HCY08. Should they be positive, then Phase III trials would most likely be initiated.
- **Light sensitivity secondary to a type of cancer treatment** – Photodynamic therapy (PDT) is a form of cancer therapy. PDT uses laser, or other light sources, combined with a light sensitive drug (called a photosensitising agent) to destroy cancer cells. A significant side-effect, however, is a type of light sensitivity, a debilitating photosensitivity of skin and eyes (sunlight, as well as artificial light). Essentially, this is an induced form of erythropoietic protoporphyria (EPP). Patients suffer intense pain associated with this photosensitivity and are forced to avoid light for up to 90 days following treatment. It is anticipated that CUV1647 will be shown to prevent the phototoxicity associated with photodynamic therapy (PDT) in cancer therapy. CUV has started its Phase II clinical trials of CUV1647 against this disease, and should report the results of these towards the start of 2HCY08. If positive, Phase III trials would most likely be initiated.

CUV's opportunities and timelines are shown below.

Table 1 : Timeline and probability of CUV's opportunities for CUV1647

Trial stage	Preclinical	Investigational New Drug application	Phase II trials	Clinical III trials
General time until cashflow	7 years+	5-7 years	3-5 years	1-2 years
General probability of product getting to market	c10%	c20%	c30%	c70%
Cost of trials	cA$1m	cA$2-3m	cA$10m	cA$50m
MSB products - indications and stages of development				
Polymorphous light eruption (PMLE) trial	→	→	→	→
Erythropoietic porphyria (EPP) trial	→	→	→	→
Skin cancer trial - all cancers apart from melanoma	→	→	→	
Solar urticaria (SU) trial	→	→	→	
Light sensitivity associated with cancer treatment	→	→	→	

Source: Company data, ABN AMRO estimates

Buy recommendation maintained; price target A$1.15

Our DCF valuation and target price remains at A$1.15. Upside risks include the faster-than-expected progression to production of CUV's photoprotective technology, while downside risks include any delay or failure to progress clinical trials.

On an industry-wide basis, the chances of getting a product to market from the Phase III stage are in the order of 70%. As a result, we believe the odds that CUV will be able get CUV1647 to market are better than even. CUV management will need to balance the use of funds to progress a number of projects through regulatory pathways against the increased cash flow that this would entail. Hence, we believe CUV is an investment opportunity for investors with a higher risk appetite.

CUV – financial summary

Year to 30 Jun (A$m)	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS
Income statement	**2006A**	**2007A**	**2008F**	**2009F**	**2010F**
Divisional sales	0.0	0.0	0.0	0.0	14.2
Total revenue	0.8	0.3	0.4	0.5	14.8
EBITDA	-10.3	-10.6	-14.4	-12.3	-2.5
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation	-0.9	-0.8	-0.9	-0.9	-1.0
EBITA	-11.2	-11.4	-15.3	-13.2	-3.4
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0
EBIT	-11.2	-11.4	-15.3	-13.2	-3.4
EBIT(incl associate profit)	-11.2	-11.4	-15.3	-13.2	-3.4
Net interest expense	0.4	2.2	1.6	0.9	0.5
Pre-tax profit	-10.8	-9.2	-13.6	-12.2	-2.9
Income tax expense	0.0	0.0	0.0	0.0	0.0
After-tax profit	-10.8	-9.2	-13.6	-12.2	-2.9
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT pre significant items	-10.8	-9.2	-13.6	-12.2	-2.9
Significant items	0.0	0.0	0.0	0.0	0.0
Reported NPAT	-10.8	-9.2	-13.6	-12.2	-2.9

Cash flow statement	**2006A**	**2007A**	**2008F**	**2009F**	**2010F**
EBITDA	-10.3	-10.6	-14.4	-12.3	-2.5
Change in working capital	0.0	0.0	0.4	0.5	0.6
Net interest (pd)/rec	0.4	2.0	1.6	0.9	0.5
Taxes paid	0.5	0.4	0.0	0.0	0.0
Other oper cash items	-2.0	0.0	0.0	0.0	0.0
Cash flow from ops (1)	-11.4	-8.2	-12.4	-10.8	-1.4
Capex (2)	0.0	-0.2	-0.1	-0.2	-0.2
Disposals/(acquisitions)	-2.3	-26.7	-0.3	-0.3	-0.3
Other investing cash flow	0.0	0.4	0.0	0.0	0.0
Cash flow from invest (3)	-2.4	-26.5	-0.4	-0.4	-0.4
Incr/(decr) in equity	18.3	60.0	0.0	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	-0.7	0.0	0.0	0.0	0.0
Cash flow from fin (5)	17.6	60.0	0.0	0.0	0.0
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	3.8	25.4	-12.8	-11.2	-1.8
Equity FCF (1+2+4)	-11.4	-8.4	-12.5	-11.0	-1.5

Balance sheet	**2006A**	**2007A**	**2008F**	**2009F**	**2010F**
Cash & deposits	8.6	33.8	21.1	9.8	8.1
Trade debtors	0.2	0.2	0.3	0.3	0.4
Inventory	0.6	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0
Other intangible assets	2.9	2.2	1.6	1.1	0.5
Fixed assets	0.2	0.3	0.4	0.5	0.6
Other assets	4.5	31.2	31.2	31.2	31.2
Total assets	17.1	67.8	54.6	43.0	40.7
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	3.0	2.3	2.8	3.3	4.0
Long-term borrowings	0.0	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.1	0.1	0.1	0.1	0.1
Total liabilities	3.1	2.4	2.9	3.5	4.1
Preference shares					
Hybrid equity					
Share capital	52.7	112.8	112.8	112.8	112.8
Other reserves	1.2	1.6	1.6	1.6	1.6
Retained earnings	-39.9	-49.1	-62.7	-75.0	-77.9
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	14.0	65.4	51.7	39.5	36.6
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	14.0	65.4	51.7	39.5	36.6
Total liabilities & SE	17.1	67.8	54.6	43.0	40.7

Closing price (A$)	**0.35**	**Price target (A$)**	**1.15**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$ 1.16
DCF valuation inputs			
Rf	5.75%	10-year rate	5.75%
Rm-Rf	4.50%	Margin	2.0%
Beta	1.50	Kd	7.75%
CAPM (Rf+Beta(Rm-Rf))	12.5%	Ke	12.5%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	315.8
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-33.8
Interest rate	7.75%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	349.7
WACC	12.5%	Diluted no. of shares (m)	302.1
		DCF valuation (A$)	**1.16**

Multiples	**2007A**	**2008F**	**2009F**	**2010F**
Enterprise value (A$m)	74.9	87.7	98.9	100.7
EV/Sales (x)				7.1
EV/EBITDA (x)				
EV/EBIT (x)	-6.6	-5.7	-7.5	-29.2
PE (normalised) (x)				
PEG (normalised) (x)				

At target price	**2007A**	**2008F**	**2009F**	**2010F**
EV/EBITDA (x)	-29.6	-22.6	-27.5	-136.2
PE (normalised) (x)	-31.1	-25.5	-28.4	-119.4

Comparable company data (x)		**2008F**	**2009F**	**2010F**
Mesoblast	EV/EBITDA	-12.0	-9.9	103.3
Year to 30 Jun	EV/EBIT	-11.9	-9.9	-2282.1
	PE	-10.6	-10.5	-102.7
	PEG			
Alchemia	EV/EBITDA	-5.8	-105.5	1.1
Year to 30 Jun	EV/EBIT	-5.0	-24.8	1.1
	PE	-5.9	-40.0	1.3
	PEG	-1.7	-11.4	0.4

Per share data	**2007A**	**2008F**	**2009F**	**2010F**
No. shares	302.1	302.1	302.1	302.1
EPS (cps)	-3.7	-4.5	-4.1	-1.0
EPS (normalised) (c)	-3.7	-4.5	-4.1	-1.0
Dividend per share (c)	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0	0.0	0.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0

Growth ratios	**2007A**	**2008F**	**2009F**	**2010F**
Sales growth	na	na	na	na
Operating cost growth	2.8%	36.2%	-15.0%	36.3%
EBITDA growth	2.8%	36.2%	-15.0%	-79.7%
EBITA growth	1.8%	34.0%	-13.9%	-73.8%
EBIT growth	1.8%	34.0%	-13.9%	-73.8%
Norm. NPAT growth (pre GW)	-14.8%	48.7%	-10.3%	-76.2%
Norm. NPAT growth	-14.8%	48.7%	-10.3%	-76.2%
Norm. EPS growth (pre GW)	-46.2%	22.2%	-10.3%	-76.2%
Norm. EPS growth	-46.2%	22.2%	-10.3%	-76.2%

Operating performance	**2007A**	**2008F**	**2009F**	**2010F**
Asset turnover (%)	0.0	0.0	0.0	8.5
EBITDA margin (%)	na	na	na	-17.5
EBIT margin (%)	na	na	na	-24.2
Net profit margin (%)	na	na	na	-20.5
Return on net assets (%)	-17.5	-29.6	-33.3	-9.4
Net debt (A$m)	-33.8	-21.1	-9.8	-8.1
Net debt/equity (%)	-51.8	-40.7	-24.9	-22.0
Net interest/EBIT cover (x)	5.1	9.3	14.2	6.4
ROIC (%)	-148.4	-33.9	-30.1	-8.1

Internal liquidity	**2007A**	**2008F**	**2009F**	**2010F**
Current ratio (x)	26.9	18.2	12.0	9.7
Receivables turnover (x)	na	0.0	0.0	37.2
Payables turnover (x)	na	5.7	4.0	4.6

Source: Company data, ABN AMRO estimates

DISCLOSURES APPENDIX

Recommendation structure

Absolute performance, short term (trading) recommendation: A Trading Buy recommendation implies upside of 5% or more and a Trading Sell indicates downside of 5% or more. The trading recommendation time horizon is 0-60 days. For Australian coverage, a Trading Buy recommendation implies upside of 5% or more from the suggested entry price range, and a Trading Sell recommendation implies downside of 5% or more from the suggested entry price range. The trading recommendation time horizon is 0-60 days.

Absolute performance, long term (fundamental) recommendation: The recommendation is based on implied upside/downside for the stock from the target price. A Buy/Sell implies upside/downside of 10% or more and a Hold less than 10%. For listed property trusts (LPT) or real estate investment trusts (REIT) the recommendation is based upon the target price plus the dividend yield, ie total return. This structure applies to research on Asian and European stocks published from 1 November 2005; on Australian stocks from 7 November 2006; on continental European small and mid cap stocks from 23 November 2006; and on Brazilian stocks from 18 June 2007.

Performance parameters and horizon: Given the volatility of share prices and our pre-disposition not to change recommendations frequently, these performance parameters should be interpreted flexibly. Performance in this context only reflects capital appreciation and the horizon is 12 months.

Sector relative to market: The sector view relative to the market is the responsibility of the strategy team. Overweight/Underweight implies upside/downside of 10% or more and Neutral implies less than 10% upside/downside.

Target price: The target price is the level the stock should currently trade at if the market were to accept the analyst's view of the stock and if the necessary catalysts were in place to effect this change in perception within the performance horizon. In this way, therefore, the target price abstracts from the need to take a view on the market or sector. If it is felt that the catalysts are not fully in place to effect a re-rating of the stock to its warranted value, the target price will differ from 'fair' value.

Asset allocation: The asset allocation is the responsibility of the economics team. The recommended weight (Over, Neutral and Under) for equities, cash and bonds is based on a number of metrics and does not relate to a particular size change in one variable.

Stock borrowing rating: The stock borrowing rating is the subjective view and responsibility of the ABN AMRO equity finance team: Easy implies ready availability. Moderate implies some availability. Hard implies availability is tight. Impossible implies no availability.

Distribution of recommendations

The tables below show the distribution of ABN AMRO's recommendations (both long term and trading). The first column displays the distribution of recommendations globally and the second column shows the distribution for the region. Numbers in brackets show the percentage for each category where ABN AMRO has an investment banking relationship.

Long Term recommendations (as at 31 Jan 2008)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	593 (15)	380 (3)
Add	0 (0)	0 (0)
Hold	413 (19)	244 (5)
Reduce	0 (0)	0 (0)
Sell	76 (11)	51 (4)
Total (IB%)	**1082 (16)**	**675 (4)**

Trading recommendations (as at 31 Jan 2008)

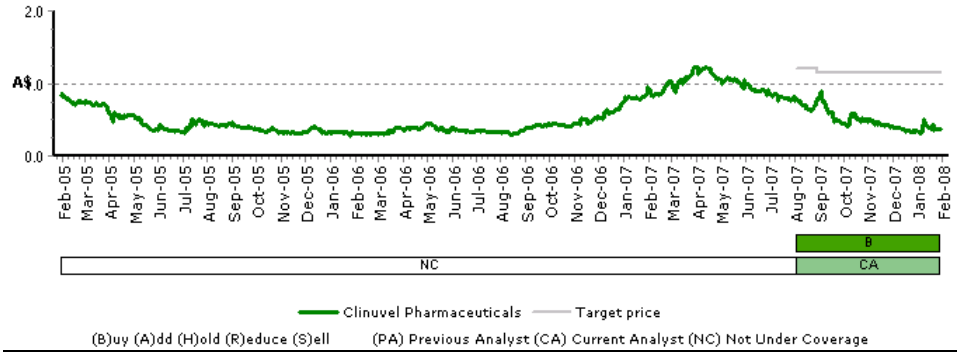
	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	8 (0)	6 (0)
Trading Sell	0 (0)	0 (0)
Total (IB%)	**8 (0)**	**6 (0)**

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.355, TP: A$1.15): Our valuation of CUV is based on a discounted cash flow model, from which we derive our target price. Upside risks include the faster-than-expected progression to production of CUV's anti-skin allergy technology, while downside risks include any delay or failure to progress clinical trials.

Clinuvel Pharmaceuticals

Stock performance, recommendations and coverage (as at 30 Jan 2008)



Dr David Stanton started covering this stock on 2 Aug 07
New recommendation structure from 7 November 2005

Trading recommendation history (as at 31 Jan 2008)

Date	Rec	Analyst
	n/a	

Regulatory disclosures

Subject companies: **CUV.AX**

DISCLOSURES APPENDIX

Global disclaimer

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