

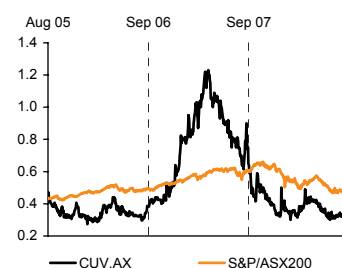
29 August 2008

Produced and issued by: ABN AMRO Equities Australia Ltd

Change of target price

**Buy**Target price  
A\$1.00 (from A\$0.95)Price  
A\$0.300Short term (0-60 days)  
n/a**Price performance**

	(1M)	(3M)	(12M)
Price (A\$)	0.32	0.40	0.79
Absolute %	-6.2	-25.0	-62.0
Rel market %	-7.0	-14.5	-53.1
Rel sector %	-10.0	-25.4	-59.1

Market capitalisation  
A\$90.71m (US\$77.85m)Average (12 mnt) daily turnover  
A\$0.18m (US\$0.16m)RIC: CUV.AX, CUV AU  
Priced at close of business 29 Aug 2008.  
Source: Bloomberg**Analysts**

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# Clinuvel Pharmaceuticals

## FY08 - stretching for the tape

**CUV posted NPAT in line with our forecast. In FY09, CUV hopes to further progress its lead compound, afamelanotide, against a number of sun-related diseases, including PMLE. We believe cash flow from sales is likely sooner than most other biotechs.**

**Key forecasts**

	FY07A	FY08A	FY09F	FY10F	FY11F
EBITDA (A\$m)	-10.6	-17.1	-13.1 ▼	-4.79 ▼	4.22
Reported net profit (A\$m)	-9.18	-14.7	-12.8	-4.13 ▲	3.42
Normalised net profit (A\$m) <sup>1</sup>	-9.18	-13.6	-12.8	-4.13 ▲	3.42
Normalised EPS (c) <sup>1</sup>	-3.70	-4.51	-4.21	-1.36 ▲	1.13
Normalised EPS growth (%)	-46.2	21.9	-6.58	-67.6	n/a
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	26.6
EV/EBITDA (x)	n/m	n/m	n/m	n/m	18.0
Price/net oper. CF (x)	-9.10	-12.6	-8.09 ▲	-26.4 ▲	21.5 ▼
ROIC (%)	-148.4	-39.8	-37.5	-13.8	11.9

Use of ▲ ▼ indicates that the line item has changed by at least 5%.

year to Jun, fully diluted

1. Pre non-recurring items and post preference dividends

Accounting Standard: IFRS

Source: Company data, ABN AMRO forecasts

**FY08 result in line with forecasts**

CUV posted normalised NPAT of -A\$13.6m for FY08, in line with our forecast of -A\$13.5m. The differences to our forecasts related to a lower-than-expected cash burn, but higher-than-expected interest expense. The net operating cash outflow was A\$7.2m, compared to our forecast outflow of A\$12.3m. CUV is well cashed-up (A\$53.1m in cash and other current assets as at 30 June 2008) to fund its clinical programme. We have made no changes to our model assumptions in terms of take-up of afamelanotide in its major markets, and have maintained our rate of cash burn as CUV enters its clinical programme phase. Finally, we have updated future operating expenses in line with the FY08 result.

**In FY09, CUV hopes to progress its lead compound afamelanotide**

CUV aims to show its lead compound has efficacy against a number of sun-related diseases. Afamelanotide is a slow-release deposit of alpha-melanocyte-stimulating hormone (alpha-MSH) and induces melanogenesis, a process by which the skin's tanning cells (melanocytes) produce the skin's tanning pigment (melanin). Essentially, melanin has been shown to increase protection from the sun (photoprotection) and decrease the ageing effects of the sun (photoageing).

**CUV's trials are relatively well advanced**

CUV has two trials in Phase III. 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 afamelanotide to market are better than even. Hence, cash flow from sales is likely, and sooner than most other biotechnology companies, in our view.

**Buy maintained, target price raised to A\$1.00**

As a result of our changes, our DCF valuation and target price have increased by 5.3% to A\$1.00 (from A\$0.95). Short-term catalysts include a completion of the current EU Phase III EPP trial. If successful, CUV would seek authority for afamelanotide in EPP - the final regulatory step before the start of sales.

**Important disclosures can be found in the Disclosures Appendix.**

## The result

CUV posted normalised NPAT of -A\$13.6m for FY08, in line with our forecast of -A\$13.5m. The differences to our forecasts related to a lower-than-expected cash burn, but higher-than-expected interest expense. The net operating cash outflow was A\$7.2m, compared to our forecast outflow of A\$12.3m. CUV is well cashed-up (A\$53.1m in cash and other current assets as at 30 June 2008) to fund its clinical program. We have made no changes to our model assumptions in terms of take-up of afamelanotide in its major markets, and have maintained our rate of cash burn as CUV enters its clinical programme phase. Finally, we have updated future operating expenses in line with the FY08 result. The changes to our forecasts are shown below.

**Table 1 : CUV – Changes to forecasts**

	FY08F			FY09F			FY10F		
	Fcast	Actual	Diff	Prev	Rev	Diff	Prev	Rev	Diff
EBIT (A\$m)	-16.3	-17.9	10.0%	-13.2	-14.0	6.0%	-4.9	-4.9	-0.5%
NPAT (A\$m)	-13.5	-13.6	0.6%	-12.2	-12.8	4.3%	-4.4	-4.1	5.3%
EPS (c)	-4.5	-4.5	0.5%	-4.0	-4.2	3.9%	-1.4	-1.4	5.6%
DPS (c)	0.0	0.0	nm	0.0	0.0	nm	0.0	0.0	nm
Net op cash flow (A\$m)	-12.3	-7.2	-41.4%	-10.8	-11.2	3.8%	-2.8	-3.4	-22.4%

Source: ABN AMRO

## What is afamelanotide?

CUV aims to show its lead compound, afamelanotide, has efficacy against a number of sun-related diseases. Afamelanotide is administered via an injection under the skin of a slow-release deposit of alpha-melanocyte-stimulating hormone (alpha-MSH) and induces melanogenesis, a process by which the skin's tanning cells (melanocytes) produce the skin's tanning pigment (melanin). Essentially, melanin has been shown to increase protection from the sun (photoprotection) and decrease the ageing effects of the sun (photoageing).

Afamelanotide is administered underneath the skin as an injectable, fully dissolvable implant, about the size of a grain of rice. The implant releases slowly over 10-15 days, releasing a supply of afamelanotide into the body. In the current implant, we believe that over a 10-day period a total of 16mg of afamelanotide is administered via the subcutaneous implant.

## Key takeaways

- **CUV's trials are relatively advanced** – CUV has two trials in Phase III. 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 afamelanotide to market are better than even. Hence, cash flow from sales is likely, and sooner than most other biotechnology companies.
- **Afamelanotide continues to receive ODD** – CUV has previously announced that its photoprotective drug afamelanotide (previously known as CUV1647) has been granted orphan-drug designation (ODD) by the US FDA for the treatment of erythropoietic porphyrias (EP). There are essentially two erythropoietic porphyrias: 1) Erythropoietic Protoporphyria (EPP) - absolute sun allergy; and 2) Congenital Erythropoietic Porphyria (CEP) - a congenital form of absolute sun allergy. This gives the FDA the right to utilise afamelanotide in the management of erythropoietic porphyrias, which affect less than 200,000 patients in the US. In the US, an orphan drug is any drug developed under the Orphan Drug Act (ODA) of January 1983, a federal law concerning rare diseases ('orphan diseases'), defined as diseases affecting fewer than 200,000 people in the US, or low prevalence, taken as prevalence of less than five per 10,000 in the community. Because medical research and the development of drugs to treat such diseases is financially disadvantageous, companies that do so are rewarded with tax reductions and marketing exclusivity on that drug for an extended time (seven years post-approval). The concept behind the ODA is that the longer period of exclusivity will encourage more companies to invest money in research. Should afamelanotide prove advantageous in the treatment of EPP, CUV will receive seven years of marketing exclusivity for its product to treat this disease.
- **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 a number of sun-related disorders.

- **Strong levels of cash** – CUV has a cash and other assets position of A\$53.1m. We believe CUV has potentially valuable opportunities and believe it unlikely, given current levels of cash, that CUV will need to raise equity to progress its trials. In FY09, we forecast that cash burn will be cA\$1.0m per month (=A\$11.7m pa) as CUV enters clinical trials for its afamelanotide product.

### Buy maintained; price target raised to A\$1.00

As a result of our changes, our DCF valuation and target price have increased by 5.3% to A\$1.00 (from A\$0.95). 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 afamelanotide to market are better than even. In our view, 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 opportunity for investors with a higher risk appetite.

**Chart 1 : Timeline and probability of CUV's opportunities for afamelanotide**

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
<b>MSB products - indications and stages of development</b>				
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: ABN AMRO estimates, company data

### Changes to forecasts

We have made no changes to our model assumptions in terms of take-up of afamelanotide in its major markets.

- **Rate of cash burn** – We have maintained our rate of cash burn as CUV enters its clinical programme phase. In FY09, we forecast that cash burn will be cA\$1.0m per month (=A\$11.7m per year), as CUV enters clinical trials for its afamelanotide product. This clinical programme continues into FY10;
- **Operating expenses** – We have updated our forecast future operating expenses in line with the FY08 result;
- **Forecast period** – We have rolled forward our 10-year forecast period; and,
- **Net interest expense** – This has been adjusted for balances at the end of period.

### Our market forecasts

- **Market size in FY10** – We forecast the potential population market size for PMLE will be 130m in FY10. Assuming a 1% penetration rate and wholesale price per implant of US\$350, we estimate the potential economic market size at US\$227m in FY10.
- **Probability of getting to market** – We believe there is a 70% chance of afamelanotide getting to market. This probability is likely to increase as CUV progresses through Phase III clinical trials. We believe CUV is unlikely to begin realising revenue until FY10.
- **Royalty assumptions** – For its PMLE opportunity, we forecast CUV will decide to enter into an agreement with a larger pharmaceutical partner to carry out marketing and distribution. We expect CUV to agree to a royalty from sales of the finished product, including an upfront payment and, on that basis, assume CUV will receive a 10% royalty rate on sales of afamelanotide. This is in line with royalty rates that, from our research, have been negotiated recently between biotech companies and global pharmaceutical companies. For its EPP opportunity, we believe initially CUV is likely to sell its product directly to patients, as the market opportunity is much smaller.
- **CUV market share** – Our analysis suggests CUV is likely to be the first player in this market

for some time. Hence, we assume CUV's market share will be high initially, at 50% of the available market. We believe the major competition to CUV's product is likely to come from Magen BioSciences, a privately owned biotechnology company focused on skin diseases.

- **Selling price** – We assume an initial selling price of US\$350 per implant and that this will decline by 2% pa. At present, the average reimbursement per depot injection is about US\$175 (not designed for skin cancer). However, these injections have been on the market for an average of six years, and therefore we believe afamelanotide will be able to command a price premium.
- **Gross profit margin assumptions** – In line with most pharmaceutical companies, we assume CUV achieves a steady-state gross profit margin of 70%.

## CUV – financial summary

Year to 30 Jun (A\$m)	AIFRS 2007A	AIFRS 2008A	AIFRS 2009F	AIFRS 2010F	AIFRS 2011F	Closing price (A\$)	0.30	Price target (A\$)	1.00
<b>Income statement</b>						<b>Valuation metrics</b>			
Divisional sales	0.0	0.0	0.0	12.2	25.3	Preferred methodology	DCF	Val'n (A\$)	\$ 1.00
Total revenue	0.3	0.0	0.5	12.7	26.0	<b>DCF valuation inputs</b>			
EBITDA	-10.6	-17.1	-13.1	-4.8	4.2	Rf	6.50%	10-year rate	6.50%
Associate income	0.0	0.0	0.0	0.0	0.0	Rm-Rf	4.50%	Margin	2.0%
Depreciation/Amortisation	-0.8	-0.8	-0.9	-0.1	-0.1	Beta	1.50	Kd	8.50%
EBITA	-11.4	-17.9	-14.0	-4.9	4.1	CAPM (Rf+Beta(Rm-Rf))	13.3%	Ke	13.2%
Goodwill Amortisation	0.0	0.0	0.0	0.0	0.0	E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A\$m)	276.7
EBIT	-11.4	-17.9	-14.0	-4.9	4.1	Equity (E/EV)	100.0%	Minority interest (A\$m)	0.0
EBIT(incl associate profit)	-11.4	-17.9	-14.0	-4.9	4.1	Debt (D/EV)	0.0%	Net debt (A\$m)	-25.8
Net interest expense	2.2	4.3	1.2	0.8	0.8	Interest rate	8.50%	Investments (A\$m)	0.0
Pre-tax profit	-9.2	-13.6	-12.8	-4.1	4.9	Tax rate (t)	30.0%	Equity market value (A\$m)	302.4
Income tax expense	0.0	0.0	0.0	0.0	-1.5	<b>WACC</b>	13.2%	Diluted no. of shares (m)	303.1
After-tax profit	-9.2	-13.6	-12.8	-4.1	3.4			<b>DCF valuation (A\$)</b>	<b>1.00</b>
Minority interests	0.0	0.0	0.0	0.0	0.0				
NPAT pre significant items	-9.2	-13.6	-12.8	-4.1	3.4	<b>Multiples</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>
Significant items	0.0	-1.0	0.0	0.0	0.0	Enterprise value (A\$m)	71.0	82.4	86.1
Reported NPAT	-9.2	-14.7	-12.8	-4.1	3.4	EV/Sales (x)			7.1
						EV/EBITDA (x)	n/a	n/a	n/a
<b>Cash flow statement</b>	<b>2007A</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>	<b>2011F</b>	EV/EBIT (x)	n/a	n/a	n/a
EBITDA	-10.6	-17.1	-13.1	-4.8	4.2	PE (normalised) (x)	n/a	n/a	n/a
Change in working capital	0.0	0.0	0.6	0.6	0.7	PEG (normalised) (x)			28.4
Net interest (pd)/rec	2.0	4.0	1.2	0.8	0.8				
Taxes paid	0.4	0.3	0.0	0.0	-1.5	<b>At target price</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>
Other oper cash items	0.0	5.6	0.0	0.0	0.0	EV/EBITDA (x)	n/a	n/a	n/a
Cash flow from ops (1)	-8.2	-7.2	-11.2	-3.4	4.2	PE (normalised) (x)	n/a	n/a	n/a
Capex (2)	-0.2	-0.2	-0.2	-0.2	-0.2				
Disposals/(acquisitions)	-26.7	-0.5	0.0	0.0	0.0	<b>Comparable company data (x)</b>	<b>2009F</b>	<b>2010F</b>	<b>2011F</b>
Other investing cash flow	0.4	0.0	0.0	0.0	0.0	Alchemia	EV/EBITDA	-4.0	7.2
Cash flow from invest (3)	-26.5	-0.7	-0.2	-0.2	-0.2	Year to 30 Jun	EV/EBIT	-3.5	10.8
Incr/(decr) in equity	60.0	0.0	0.0	0.0	0.0		PE	-4.4	5.7
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0		PEG	-1.3	1.6
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0	Mesoblast	EV/EBITDA	-13.7	-11.9
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0	Year to 30 Jun	EV/EBIT	-13.4	-11.7
Other financing cash flow	0.0	0.0	0.0	0.0	0.0		PE	-15.2	-16.3
Cash flow from fin (5)	60.0	0.0	0.0	0.0	0.0		PEG		
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0				
Inc/(decr) cash (1+3+5+6)	25.4	-7.9	-11.4	-3.6	4.0	<b>Per share data</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>
Equity FCF (1+2+4)	-8.4	-7.4	-11.4	-3.6	4.0	No. shares	303.1	303.1	303.1
						EPS (cps)	-4.8	-4.2	-1.4
<b>Balance sheet</b>	<b>2007A</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>	<b>2011F</b>	EPS (normalised) (c)	-4.5	-4.2	-1.4
Cash & deposits	33.8	25.8	14.3	10.7	14.7	Dividend per share (c)	0.0	0.0	0.0
Trade debtors	0.2	0.6	0.3	0.4	0.5	Dividend payout ratio (%)	0.0	0.0	0.0
Inventory	0.0	0.0	0.0	0.0	0.0	Dividend yield (%)	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	<b>Growth ratios</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>
Other intangible assets	2.2	1.4	0.6	0.6	0.6	Sales growth	na	na	na
Fixed assets	0.3	0.4	0.5	0.6	0.7	Operating cost growth	61.3%	-23.4%	29.8%
Other assets	31.2	26.8	26.8	26.8	26.8	EBITDA growth	61.3%	-23.4%	-63.4%
Total assets	67.8	55.0	42.6	39.1	43.3	EBIT growth	57.0%	-22.1%	-65.0%
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	Norm. NPAT growth	48.5%	-6.3%	-67.6%
Trade payables	2.3	3.0	3.3	4.0	4.8	Norm. EPS growth	21.9%	-6.6%	-67.6%
Long-term borrowings	0.0	0.0	0.0	0.0	0.0				
Provisions	0.0	0.0	0.0	0.0	0.0	<b>Operating performance</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>
Other liabilities	0.1	0.2	0.2	0.2	0.2	Asset turnover (%)	0.0	0.0	7.5
Total liabilities	2.4	3.2	3.5	4.2	5.0	EBITDA margin (%)	na	na	-39.3
Preference shares						EBIT margin (%)	na	na	-40.1
Hybrid equity						Net profit margin (%)	na	na	-33.9
Share capital	112.8	113.2	113.2	113.2	113.2	Return on net assets (%)	-34.6	-35.8	-14.0
Other reserves	1.6	1.8	1.8	1.8	1.8	Net debt (A\$m)	-25.8	-14.3	-10.7
Retained earnings	-49.1	-63.2	-75.9	-80.1	-76.6	Net debt/equity (%)	-49.7	-36.7	-30.6
Other equity	0.0	0.0	0.0	0.0	0.0	Net interest/EBIT cover (x)	4.2	11.6	6.5
Total equity	65.4	51.8	39.1	34.9	38.3	ROIC (%)	-39.8	-37.5	-13.8
Minority interest	0.0	0.0	0.0	0.0	0.0				
Total shareholders' equity	65.4	51.8	39.1	34.9	38.3	<b>Internal liquidity</b>	<b>2008A</b>	<b>2009F</b>	<b>2010F</b>
Total liabilities & SE	67.8	55.0	42.6	39.1	43.3	Current ratio (x)	16.9	11.8	9.1
						Receivables turnover (x)	na	0.0	31.9
						Payables turnover (x)	na	4.2	4.6

Source: ABN AMRO estimates, company data

## 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 UK Small/Mid-Cap Analysis a Buy/Sell implies upside/downside of 10% or more, an Add/Reduce 5-10% and a Hold less than 5%. For UK-based Investment Funds research the recommendation structure is not based on upside/downside to the target price. Rather it is the subjective view of the analyst based on an assessment of the resources and track record of the fund management company. 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.

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.

## 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 29 Aug 2008)		
	Global total (IB%)	Asia Pacific total (IB%)
Buy	527 (4)	369 (0)
Add	0 (0)	0 (0)
Hold	367 (2)	216 (0)
Reduce	0 (0)	0 (0)
Sell	95 (0)	57 (0)
Total (IB%)	989 (3)	642 (0)

Source: ABN AMRO

Trading recommendations (as at 29 Aug 2008)		
	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	4 (0)	4 (0)
Trading Sell	1 (0)	1 (0)
Total (IB%)	5 (0)	5 (0)

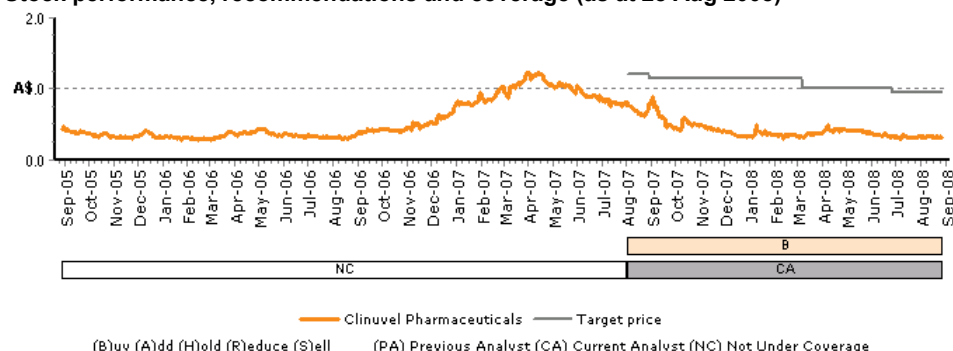
Source: ABN AMRO

## Valuation and risks to target price

**Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A\$0.300, TP: A\$1.000):** 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 photoprotective technology, while downside risks include any delay or failure to progress clinical trials.

## Clinuvel Pharmaceuticals coverage data

### Stock performance, recommendations and coverage (as at 28 Aug 2008)



### Trading recommendation history (as at 29 Aug 2008)

Date	Rec	Analyst
	n/a	

Source: ABN AMRO

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

## Regulatory disclosures

Subject companies: **CUV.AX**



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