5 March 2009

Produced and issued by: ABN AMRO Equities Australia Ltd

Clinuvel Pharmaceuticals

1H09: Major milestones achieved

CUV's 1H09 NPAT was affected by the unrealised mark-to-market valuation of financial investments. 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.

Buy

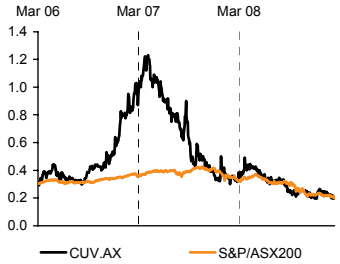
Target price
A$0.90

Price
A$0.20

Short term (0-60 days)
n/a

Price performance

	(1M)	(3M)	(12M)
Price (A$)	0.25	0.22	0.32
Absolute (%)	-18.4	-7.0	-38.5
Rel market (%)	-11.4	3.8	4.6
Rel sector (%)	-2.6	10.2	-18.3



Market capitalisation
A$60.63m (US$38.42m)

Average (12M) daily turnover
A$0.15m (US$0.12m)

RIC: CUV.AX, CUV AU
Priced at close of business 4 Mar 2009.
Source: Bloomberg

Key forecasts

	FY07A	FY08A	FY09F	FY10F	FY11F
EBITDA (A$m)	-10.6	-17.1	-19.0 ▼	-5.44 ▼	5.03 ▼
Reported net profit (A$m)	-9.18	-14.7	-17.0 ▼	-2.51 ▼	5.56 ▼
Normalised net profit (A$m)[1]	-9.18	-13.6	-16.4 ▼	-2.51 ▼	5.56 ▼
Normalised EPS (c)[1]	-3.70	-4.51	-5.41 ▼	-0.83 ▼	1.84 ▼
Normalised EPS growth (%)	-46.2	21.90	20.20	-84.7	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	10.90
EV/EBITDA (x)	n/m	n/m	n/m	n/m	8.20
Price/net oper. CF (x)	-6.07	-8.42	-5.64	-9.70 ▲	9.59 ▲
ROIC (%)	-148	-39.8	-53.4	-18.8	14.10

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

1H09 result affected by unrealised mark-to-market valuation of financial investments

CUV posted normalised NPAT of -A$8.5m for 1H09, compared with our forecast of -A$4.6m. Key reasons for the difference from our forecast related to: 1) greater R&D; 2) an unrealised currency gain; and 3) an unrealised charge associated with the mark-to-market valuation of financial investments. Net operating cash outflow was A$4.9m, compared to our forecast outflow of A$3.6m. We believe CUV has sufficient cash (A$43.3m in cash and other financial assets as at 31 December 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. We have revised future operating expenses in line with the 1H09 result. Our DCF-based valuation and target price remain unchanged at A$0.90.

Afamelanotide has recently received IND status in the US

CUV recently announced that the US Food and Drug Administration (FDA) has allowed the company's drug, afamelanotide, to proceed for clinical trials in the US under an investigational new drug (IND) process following a review of the available data on this drug. CUV will now make afamelanotide available for testing in the US, with the ultimate objective of registering the drug for patients who require it.

2009 – still lots to look out for

In 2009, CUV should: 1) receive interim results from the Phase III PLE trials being conducted outside the US; 2) receive final results from this Phase III EPP trial by 4Q; and 3) subject to the successful completion of this trial, seek EMEA marketing authorisation for afamelanotide for EPP. This would be the final regulatory step before the start of EU sales. Marketing authorisation is usually granted 9-12 months after filing in both the US and EU.

Analysts

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1H09 result

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Table 1 : CUV – Changes to forecasts

		1H09A			FY09F			FY10F	
	Fcast	Actual	Diff	Prev	Rev	Diff	Prev	Rev	Diff
EBIT (A$m)	-6.3	-10.1	-3.8	-14.0	-19.9	-5.9	-2.4	-5.5	-3.1
NPAT (A$m)	-4.6	-8.5	-3.9	-12.8	-16.4	-3.7	-1.6	-2.5	-0.9
EPS (c)	-1.5	-2.8	-1.3	-4.2	-5.4	-1.2	-0.5	-0.8	-0.3
DPS (c)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net op cash flow (A$m)	-3.6	-4.9	-1.3	-11.2	-10.8	0.5	-1.0	-6.2	-5.3

Source: ABN AMRO forecasts, company data

CUV recently announced that the US Food and Drug Administration (FDA) has allowed the company's drug, afamelanotide, to proceed for clinical trials in the US under an investigational new drug (IND) process following a review of the available data on this drug. The IND process is rigorous. CUV's data relating to the technical quality, safety and efficacy in the pharmaceutical development of afamelanotide has been approved by the US FDA. CUV will now make afamelanotide available for testing in the US, with the ultimate objective of registering the drug for patients who require it. The first US trial will consist of a confirmatory pharmacokinetic trial.

Analysis of market segments

We believe there are a number of potential market segments for afamelanotide should it get to market. These include markets based on the treatment of sun-allergy diseases by doctors. Below we analyse each of these markets in turn. Using various scientific research studies, we have calculated the potential market size of the total on-label indications for afamelanotide. By our estimates, the number of potential patients in the four markets we have characterised is more than 100m in the EU and US alone. We believe most of the patients in these markets would require treatment at least once or twice a year.

Table 2 : Potential market size of on-label use of afamelanotide in the EU and the US

Disease	Prevalence in population	Implied no. patients in EU & US (000)
Polymorphous light eruption (PMLE)	1 in 7.8	116,691
Solar urticaria	3.1 in 100,000	24
Side effects of photodynamic therapy (PDT)	1 in 3,050	257
Erythropoietic protoporphyria (EPP)	1 in 350,000	2.2
	Total	116,974

Source: ABN AMRO estimates, PubMed

1. Erythropoietic protoporphyria (EPP) and congenital erythropoietic porphyria (CEP)

Essentially, there are two erythropoietic porphyrias: 1) erythropoietic protoporphyria (EPP) – absolute sun allergy; and 2) congenital erythropoietic porphyria (CEP) – a congenital form of absolute sun allergy.

EPP is a rare genetic disorder due to a defect in red blood cell production. The resultant accumulated excess of its breakdown product, protoporphyrin, causes two principal manifestations: a skin sensitivity to light, and liver disease. There is no registry for EPP for the US, so accurate data is lacking. However, internationally, an estimated one case in 200,000-750,000 people has been reported for some western European populations (source: PubMed). By our estimates, about 2,200 sufferers in the US and EU would benefit from CUV1647 treatment for EPP.

CEP is a very rare disease found in people with fair skin. CEP patients experience extreme photosensitivity, which can lead to blistering, severe scarring and increased hair growth. Phototoxic damage and infection of damaged skin can lead to the loss of facial features and fingers. CEP is also known as Gunther's disease.

2. Polymorphous light eruption (PMLE)

We believe the PMLE market will be centred on doctors. This is due to the requirement for afamelanotide to be administered as a depot injection, which is generally performed by doctors. Discussions with industry contacts suggest PMLE is not a widely recognised disease at the GP level. At least initially we believe the diagnosis and subsequent depot injection will be performed at the specialist level. Should awareness of the product increase, we believe diagnosis and treatment could be made at the GP level.

However, for patients and GPs to be made aware of PMLE as a clinical entity, we believe there needs to be an education campaign aimed at potential patients and GPs. This would have the effect of increasing the awareness of PMLE and other sun-allergy diseases as clinical entities. Given the cost of a large marketing campaign, we believe CUV might ultimately co-ordinate such a campaign through a global partner, which could take a share of royalties.

3. Side effects of photodynamic therapy (PDT)

Using various scientific research studies, we have estimated the potential market size for side-effects of photodynamic therapy (PDT). We have looked at the prevalence of the major uses of photodynamic therapy, namely in the treatment of non-small-cell lung cancer, Barrett's oesophagus and oesophageal cancer. We have then analysed the literature to determine the use of PDT in these diseases. The literature suggests the rate of sun-allergy-related side effects is in the order of 31%, so these patients would benefit from treatment with afamelanotide. This is shown below. By our estimates, more than 250,000 people would benefit from the CUV1647 treatment to decrease the side effects of PDT.

Table 3 : Potential market size for side effects of photodynamic therapy (PDT)

	Prevalence in population	Implied no. patients EU & US (000)	Use of PDT	Prevalence of side effects	Potential no. of patients (000)
Non-small-cell lung cancer	1 in 2,000	393	10%	31%	12
Barrett's oesophagus	1 in 100	7,850	10%	31%	243
Oesophageal cancer	1 in 10,000	79	5%	31%	1
				Total	257

Source: ABN AMRO, PubMed, UN data

4. 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 started its Phase II clinical trials of afamelanotide against this disease in June 2008. By our estimates, 24,000 sufferers in the US and EU would benefit from afamelanotide treatment for solar urticaria.

Target price and risks

In 2009, CUV should: 1) receive interim results from the Phase III PLE trials being conducted outside the US; 2) receive final results from this Phase III EPP trial by 4Q; and 3) subject to the successful completion of this trial, seek EMEA marketing authorisation for afamelanotide for EPP. This would be the final regulatory step before the start of EU sales. Marketing authorisation is typically granted within 9-12 months of filing in both the US and EU.

We have made no operational changes to our forecasts for CUV. As a result, our DCF-based valuation and target price remain unchanged at A$0.90. We believe cash flow from sales is likely sooner than most other biotechs, and hence CUV warrants a premium to other biotech companies in the Australian market.

CUV – financial summary

Year to 30 Jun (A$m)	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS
Income statement	**2007A**	**2008A**	**2009F**	**2010F**	**2011F**
Divisional sales	0.0	0.0	0.0	15.7	31.2
Total revenue	0.3	0.0	1.1	16.2	31.8
EBITDA	-10.6	-17.1	-19.0	-5.4	5.0
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation/Amortisation	-0.8	-0.8	-0.9	-0.1	-0.1
EBITA	-11.4	-17.9	-19.9	-5.5	4.9
Goodwill Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-11.4	-17.9	-19.9	-5.5	4.9
EBIT(incl associate profit)	-11.4	-17.9	-19.9	-5.5	4.9
Net interest expense	2.2	4.3	3.5	3.0	3.0
Pre-tax profit	-9.2	-13.6	-16.4	-2.5	7.9
Income tax expense	0.0	0.0	0.0	0.0	-2.4
After-tax profit	-9.2	-13.6	-16.4	-2.5	5.6
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT pre significant items	-9.2	-13.6	-16.4	-2.5	5.6
Significant items	0.0	-1.0	-0.6	0.0	0.0
Reported NPAT	-9.2	-14.7	-17.0	-2.5	5.6

Cash flow statement	**2007A**	**2008A**	**2009F**	**2010F**	**2011F**
EBITDA	-10.6	-17.1	-19.0	-5.4	5.0
Change in working capital	0.0	0.0	4.8	-3.8	0.7
Net interest (pd)/rec	2.0	4.0	3.5	3.0	3.0
Taxes paid	0.4	0.3	0.0	0.0	-2.4
Other oper cash items	0.0	5.6	0.0	0.0	0.0
Cash flow from ops (1)	-8.2	-7.2	-10.8	-6.2	6.3
Capex (2)	-0.2	-0.2	-0.2	-0.2	-0.2
Disposals/(acquisitions)	-26.7	0.0	0.0	0.0	0.0
Other investing cash flow	0.4	0.0	0.0	0.0	0.0
Cash flow from invest (3)	-26.5	-0.2	-0.2	-0.2	-0.2
Incr/(decr) in equity	60.0	0.0	0.1	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	0.0	-0.5	4.7	0.0	0.0
Cash flow from fin (5)	60.0	-0.5	4.9	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)	25.4	-7.9	-6.0	-6.4	6.1
Equity FCF (1+2+4)	-8.4	-7.4	-10.9	-6.4	6.1

Balance sheet	**2007A**	**2008A**	**2009F**	**2010F**	**2011F**
Cash & deposits	33.8	25.8	19.7	13.3	19.4
Trade debtors	0.2	0.6	0.8	0.4	0.5
Inventory	0.0	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	2.2	1.4	0.6	0.6	0.6
Fixed assets	0.3	0.4	0.5	0.6	0.7
Other assets	31.2	26.8	26.8	26.8	26.8
Total assets	67.8	55.0	48.4	41.6	47.9
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	2.3	3.0	8.0	3.7	4.4
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	0.2	0.2	0.2	0.2
Total liabilities	2.4	3.2	8.1	3.9	4.6
Preference shares					
Hybrid equity					
Share capital	112.8	113.2	113.4	113.4	113.4
Other reserves	1.6	1.8	1.8	1.8	1.8
Retained earnings	-49.1	-63.2	-74.8	-77.3	-71.8
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	65.4	51.8	40.3	37.8	43.3
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	65.4	51.8	40.3	37.8	43.3
Total liabilities & SE	67.8	55.0	48.4	41.6	47.9

Closing price (A$)	**0.20**	**Price target (A$)**	**0.90**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$ 0.90
DCF valuation inputs			
Rf	6.50%	10-year rate	6.50%
Rm-Rf	4.50%	Margin	2.0%
Beta	1.50	Kd	8.50%
CAPM (Rf+Beta(Rm-Rf))	13.3%	Ke	13.2%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	247.1
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-25.8
Interest rate	8.50%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	272.8
WACC	13.2%	Diluted no. of shares (m)	303.1
		DCF valuation (A$)	**0.90**

Multiples	**2008A**	**2009F**	**2010F**	**2011F**
Enterprise value (A$m)	34.9	40.9	47.4	41.2
EV/Sales (x)			3.0	1.3
EV/EBITDA (x)	-2.0	-2.2	-8.7	8.2
EV/EBIT (x)	-1.9	-2.1	-8.6	8.4
PE (normalised) (x)	-4.4	-3.7	-24.2	10.9
PEG (normalised) (x)				

At target price	**2008A**	**2009F**	**2010F**	**2011F**
EV/EBITDA (x)	-14.5	-13.3	-47.7	50.4
PE (normalised) (x)	-20.0	-16.6	-108.8	49.0

Comparable company data (x)		**2009F**	**2010F**	**2011F**
Alchemia	EV/EBITDA	-2.3	-6.6	4.7
Year to 30 Jun	EV/EBIT	-1.9	-4.6	7.4
	PE	-3.1	-2.9	2.5
	PEG	-0.9	-0.8	0.7
Mesoblast	EV/EBITDA	-7.2	-6.0	6.1
Year to 30 Jun	EV/EBIT	-7.1	-5.9	7.4
	PE	-9.6	-10.8	29.5
	PEG			

Per share data	**2008A**	**2009F**	**2010F**	**2011F**
No. shares	303.1	303.1	303.1	303.1
EPS (cps)	-4.8	-5.6	-0.8	1.8
EPS (normalised) (c)	-4.5	-5.4	-0.8	1.8
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	**2008A**	**2009F**	**2010F**	**2011F**
Sales growth	na	na	na	na
Operating cost growth	na	na	na	na
EBITDA growth	na	na	na	na
EBIT growth	na	na	na	na
Norm. NPAT growth	na	na	na	na
Norm. EPS growth	na	na	na	na

Operating performance	**2008A**	**2009F**	**2010F**	**2011F**
Asset turnover (%)	0.0	0.0	8.7	17.4
EBITDA margin (%)	na	na	-34.5	16.1
EBIT margin (%)	na	na	-35.1	15.8
Net profit margin (%)	na	na	-15.9	17.9
Return on net assets (%)	-34.6	-49.3	-14.6	11.4
Net debt (A$m)	-25.8	-19.7	-13.3	-19.4
Net debt/equity (%)	-49.7	-48.9	-35.1	-44.7
Net interest/EBIT cover (x)	4.2	5.7	1.8	-1.6
ROIC (%)	-39.8	-53.4	-18.8	14.1

Internal liquidity	**2008A**	**2009F**	**2010F**	**2011F**
Current ratio (x)	16.9	5.8	10.5	10.2
Receivables turnover (x)	na	0.0	26.0	73.9
Payables turnover (x)	na	3.5	3.6	6.5

Source: ABN AMRO forecasts, 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 05 Mar 2009)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	461 (5)	290 (0)
Add	0 (0)	0 (0)
Hold	396 (1)	246 (0)
Reduce	0 (0)	0 (0)
Sell	162 (1)	102 (1)
Total (IB%)	1019 (3)	638 (0)

Source: ABN AMRO

Trading recommendations (as at 05 Mar 2009)

	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	3 (0)	3 (0)
Trading Sell	1 (0)	1 (0)
Total (IB%)	4 (0)	4 (0)

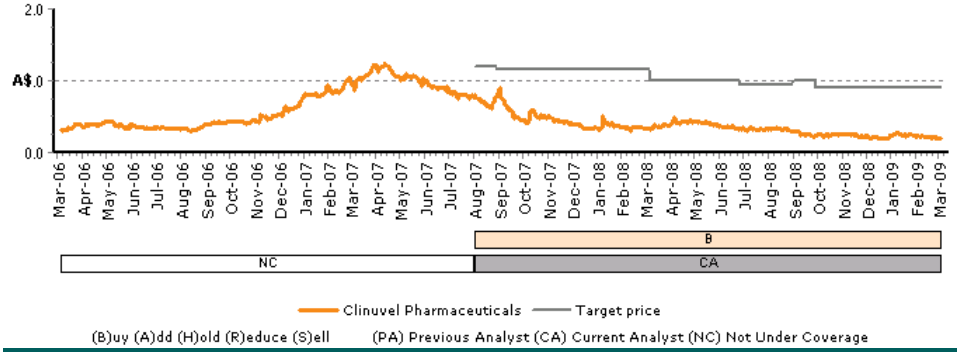
Source: ABN AMRO

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.200, TP: A$0.90): 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 4 Mar 2009)



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

Trading recommendation history (as at 05 Mar 2009)

Date	Rec	Analyst
	n/a	

Source: ABN AMRO

Regulatory disclosures

Subject companies: **CUV.AX**

Global disclaimer

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