

30 January 2009

Produced and issued by: ABN AMRO Equities Australia Ltd

Clinuvel Pharmaceuticals

CUV receives US IND status

Buy

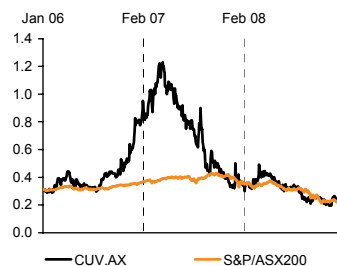
Target price
A\$0.90

Price
A\$0.24

Short term (0-60 days)
n/a

Price performance

	(1M)	(3M)	(12M)
Price (A\$)	0.19	0.25	0.37
Absolute (%)	23.1	-5.9	-34.2
Rel market (%)	26.4	1.7	6.6
Rel sector (%)	28.9	-18.2	-23.2



Market capitalisation
A\$72.76m (US\$48.00m)

Average (12M) daily turnover
A\$0.15m (US\$0.13m)

RIC: CUV.AX, CUV.AU
Priced at close of business 29 Jan 2009.
Source: Bloomberg

Analysts

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CUV's drug, afamelanotide, has received IND status in the US. CUV now has regulatory approval to enter the largest potential market for its drug. Given the near-term potential cash flow, we continue to believe CUV warrants a premium to many other biotechs. We maintain our Buy recommendation.

Key forecasts

	FY07A	FY08A	FY09F	FY10F	FY11F
EBITDA (A\$m)	-10.6	-17.1	-13.1	-2.30	8.30
Reported net profit (A\$m)	-9.18	-14.7	-12.8	-1.57	6.45
Normalised net profit (A\$m) ¹	-9.18	-13.6	-12.8	-1.57	6.45
Normalised EPS (c) ¹	-3.70	-4.51	-4.21	-0.52	2.13
Normalised EPS growth (%)	-46.2	21.90	-6.58	-87.7	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	11.30
EV/EBITDA (x)	n/m	n/m	n/m	n/m	6.32
Price/net oper. CF (x)	-7.28	-10.1	-6.47	-82.7	10.00
ROIC (%)	-148	-39.8	-37.5	-6.79	23.70

1. Pre non-recurring items and post preference dividends

year to Jun, fully diluted

Accounting standard: IFRS

Source: Company data, ABN AMRO forecasts

Afamelanotide has received IND status in the US

CUV 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 extend its current development program of the drug to the US. The first US trial will consist of a confirmatory pharmacokinetic trial.

Demonstrates the efficacy and safety of CUV's product

The IND process is rigorous. CUV's data relating to the technical quality, safety and efficacy in the pharmaceutical development of afamelanotide have 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.

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 nine to 12 months after filing in both the US and EU.

Buy recommendation, target price A\$0.90

We have not changed our forecasts as a result of this news, as it is in line with our timelines. We believe this is a large step forward for the company in that CUV now has regulatory approval to enter the largest potential market for afamelanotide. This news should remove investor fears regarding CUV being unable to enter the US market. In addition, we believe it may open up further opportunities for CUV, such as partnering and possible distribution.

Important disclosures can be found in the Disclosures Appendix.

CUV receives IND status in the US

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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 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 1 : Market size EU and US – on-label use of afamelanotide

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 suffers 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 2 : 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 number 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 estimates, 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 nine to 12 months of filing in both the US and EU.

We have not changed our forecasts as a result of this news, as it is in line with our timelines. We believe this is a large forward step for the company in that CUV now has regulatory approval to enter the largest potential market for afamelanotide. This news should remove investor fears regarding CUV being unable to enter the US market. In addition, we believe it may open up further opportunities for CUV, such as partnering and possible distribution. We maintain our target price of A\$0.90 and our Buy recommendation.

CUV – financial summary

Year to 30 Jun (A\$m)	AIFRS 2007A	AIFRS 2008A	AIFRS 2009F	AIFRS 2010F	AIFRS 2011F	Closing price (A\$)	0.24	Price target (A\$)	0.90	
Income statement						Valuation metrics				
Divisional sales	0.0	0.0	0.0	15.7	31.2	Preferred methodology	DCF	Val'n (A\$)	\$ 0.90	
Total revenue	0.3	0.0	0.5	16.3	31.8	DCF valuation inputs				
EBITDA	-10.6	-17.1	-13.1	-2.3	8.3	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	-2.4	8.2	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)	247.1	
EBIT	-11.4	-17.9	-14.0	-2.4	8.2	Equity (E/EV)	100.0%	Minority interest (A\$m)	0.0	
EBIT(incl associate profit)	-11.4	-17.9	-14.0	-2.4	8.2	Debt (D/EV)	0.0%	Net debt (A\$m)	-25.8	
Net interest expense	2.2	4.3	1.2	0.8	1.0	Interest rate	8.50%	Investments (A\$m)	0.0	
Pre-tax profit	-9.2	-13.6	-12.8	-1.6	9.2	Tax rate (t)	30.0%	Equity market value (A\$m)	272.8	
Income tax expense	0.0	0.0	0.0	0.0	-2.8	WACC	13.2%	Diluted no. of shares (m)	303.1	
After-tax profit	-9.2	-13.6	-12.8	-1.6	6.4			DCF valuation (A\$)	0.90	
Minority interests	0.0	0.0	0.0	0.0	0.0					
NPAT pre significant items	-9.2	-13.6	-12.8	-1.6	6.4	Multiples	2008A	2009F	2010F	2011F
Significant items	0.0	-1.0	0.0	0.0	0.0	Enterprise value (A\$m)	47.0	58.4	59.5	52.4
Reported NPAT	-9.2	-14.7	-12.8	-1.6	6.4	EV/Sales (x)			3.8	1.7
						EV/EBITDA (x)	-2.8	-4.5	-25.8	6.3
Cash flow statement	2007A	2008A	2009F	2010F	2011F	EV/EBIT (x)	-2.6	-4.2	-24.8	6.4
EBITDA	-10.6	-17.1	-13.1	-2.3	8.3	PE (normalised) (x)	-5.3	-5.7	-46.4	11.3
Change in working capital	0.0	0.0	0.6	0.6	0.7	PEG (normalised) (x)				
Net interest (pd)/rec	2.0	4.0	1.2	0.8	1.0	At target price	2008A	2009F	2010F	2011F
Taxes paid	0.4	0.3	0.0	0.0	-2.8	EV/EBITDA (x)	-14.5	-19.8	-112.7	30.4
Other oper cash items	0.0	5.6	0.0	0.0	0.0	PE (normalised) (x)	-20.0	-21.4	-173.9	42.3
Cash flow from ops (1)	-8.2	-7.2	-11.2	-0.9	7.3	Comparable company data (x)	2009F	2010F	2011F	
Capex (2)	-0.2	-0.2	-0.2	-0.2	-0.2	Alchemia	EV/EBITDA	-2.1	145.7	0.7
Disposals/(acquisitions)	-26.7	-0.5	0.0	0.0	0.0	Year to 30 Jun	EV/EBIT	-1.7	-10.6	0.9
Other investing cash flow	0.4	0.0	0.0	0.0	0.0		PE	-2.7	20.7	0.6
Cash flow from invest (3)	-26.5	-0.7	-0.2	-0.2	-0.2		PEG	-0.8	5.9	0.2
Incr/(decr) in equity	60.0	0.0	0.0	0.0	0.0	Mesoblast	EV/EBITDA	-7.2	-6.0	6.1
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0	Year to 30 Jun	EV/EBIT	-7.1	-5.9	7.4
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0		PE	-9.5	-10.6	28.7
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0		PEG			
Other financing cash flow	0.0	0.0	0.0	0.0	0.0	Per share data	2008A	2009F	2010F	2011F
Cash flow from fin (5)	60.0	0.0	0.0	0.0	0.0	No. shares	303.1	303.1	303.1	303.1
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0	EPS (cps)	-4.8	-4.2	-0.5	2.1
Inc/(decr) cash (1+3+5+6)	25.4	-7.9	-11.4	-1.1	7.1	EPS (normalised) (c)	-4.5	-4.2	-0.5	2.1
Equity FCF (1+2+4)	-8.4	-7.4	-11.4	-1.1	7.1	Dividend per share (c)	0.0	0.0	0.0	0.0
						Dividend payout ratio (%)	0.0	0.0	0.0	0.0
Balance sheet	2007A	2008A	2009F	2010F	2011F	Dividend yield (%)	0.0	0.0	0.0	0.0
Cash & deposits	33.8	25.8	14.3	13.3	20.3	Growth ratios	2008A	2009F	2010F	2011F
Trade debtors	0.2	0.6	0.3	0.4	0.5	Sales growth	na	na	na	97.9%
Inventory	0.0	0.0	0.0	0.0	0.0	Operating cost growth	61.3%	-23.4%	38.0%	26.7%
Investments	0.0	0.0	0.0	0.0	0.0	EBITDA growth	61.3%	-23.4%	-82.4%	na
Goodwill	0.0	0.0	0.0	0.0	0.0	EBIT growth	57.0%	-22.1%	-82.8%	na
Other intangible assets	2.2	1.4	0.6	0.6	0.6	Norm. NPAT growth	48.5%	-6.3%	-87.7%	-511.1%
Fixed assets	0.3	0.4	0.5	0.6	0.7	Norm. EPS growth	21.9%	-6.6%	-87.7%	na
Other assets	31.2	26.8	26.8	26.8	26.8	Operating performance	2008A	2009F	2010F	2011F
Total assets	67.8	55.0	42.6	41.7	48.9	Asset turnover (%)	0.0	0.0	9.3	17.2
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	EBITDA margin (%)	na	na	-14.6	26.6
Trade payables	2.3	3.0	3.3	4.0	4.8	EBIT margin (%)	na	na	-15.2	26.3
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	Net profit margin (%)	na	na	-10.0	20.7
Provisions	0.0	0.0	0.0	0.0	0.0	Return on net assets (%)	-34.6	-35.8	-6.4	18.7
Other liabilities	0.1	0.2	0.2	0.2	0.2	Net debt (A\$m)	-25.8	-14.3	-13.3	-20.3
Total liabilities	2.4	3.2	3.5	4.2	5.0	Net debt/equity (%)	-49.7	-36.7	-35.4	-46.3
Preference shares						Net interest/EBIT cover (x)	4.2	11.6	2.9	-8.1
Hybrid equity						ROIC (%)	-39.8	-37.5	-6.8	23.7
Share capital	112.8	113.2	113.2	113.2	113.2	Internal liquidity	2008A	2009F	2010F	2011F
Other reserves	1.6	1.8	1.8	1.8	1.8	Current ratio (x)	16.9	11.8	9.7	9.6
Retained earnings	-49.1	-63.2	-75.9	-77.5	-71.1	Receivables turnover (x)	na	0.0	41.2	67.9
Other equity	0.0	0.0	0.0	0.0	0.0	Payables turnover (x)	na	4.2	4.9	5.2
Total equity	65.4	51.8	39.1	37.5	43.9					
Minority interest	0.0	0.0	0.0	0.0	0.0					
Total shareholders' equity	65.4	51.8	39.1	37.5	43.9					
Total liabilities & SE	67.8	55.0	42.6	41.7	48.9					

Source: Company data, ABN AMRO forecasts

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 30 Jan 2009)		
	Global total (IB%)	Asia Pacific total (IB%)
Buy	481 (4)	313 (0)
Add	0 (0)	0 (0)
Hold	386 (1)	245 (0)
Reduce	0 (0)	0 (0)
Sell	161 (1)	98 (1)
Total (IB%)	1028 (3)	656 (0)

Source: ABN AMRO

Trading recommendations (as at 30 Jan 2009)		
	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	2 (0)	2 (0)
Trading Sell	1 (0)	1 (0)
Total (IB%)	3 (0)	3 (0)

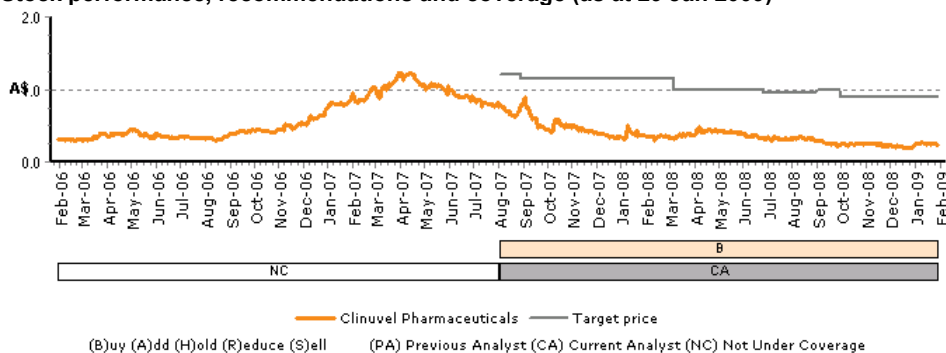
Source: ABN AMRO

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A\$0.240, 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 29 Jan 2009)



Trading recommendation history (as at 30 Jan 2009)

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

Global disclaimer

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