

9 December 2009

Produced by: RBS Equities (Australia) Limited

Clinuvel Pharmaceuticals

Continues to confirm potential

Buy

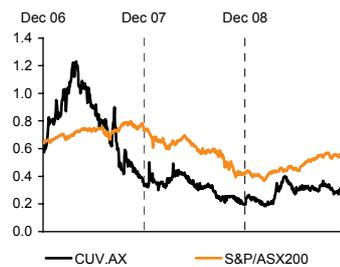
Target price
 A\$0.85

Price
 A\$0.29

Short term (0-60 days)
 n/a

Price performance

	(1M)	(3M)	(12M)
Price (A\$)	0.30	0.30	0.20
Absolute (%)	-3.3	-3.3	45.0
Rel market (%)	-4.9	-6.4	12.7
Rel sector (%)	-7.4	-5.4	41.1


Market capitalisation
 A\$87.91m (US\$80.23m)

Average (12M) daily turnover
 A\$0.09m (US\$0.07m)

 RIC: CUV.AX, CUV.AU
 Priced at close of business 8 Dec 2009.
 Source: Bloomberg

Analysts

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CUV announced it had obtained positive results from a Phase II trial evaluating afamelanotide in those who have sensitivity to UV light as a side-effect of certain cancer therapies. We await the final results from the Phase III EPP trial which, if positive, should be a big step towards EU revenues from afamelanotide.

Key forecasts

	FY08A	FY09A	FY10F	FY11F	FY12F
EBITDA (A\$m)	-17.1	-17.4	-17.9	-8.04	2.94
Reported net profit (A\$m)	-14.7	-15.6	-14.3	-5.43	4.05
Normalised net profit (A\$m) ¹	-13.6	-15.6	-14.3	-5.43	4.05
Normalised EPS (c) ¹	-4.51	-5.15	-4.70	-1.79	1.34
Normalised EPS growth (%)	21.90	14.30	-8.68	-61.9	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	21.70
EV/EBITDA (x)	n/m	n/m	n/m	n/m	25.80
Price/net oper. CF (x)	-12.2	-8.00	-6.39	-18.0	9.19
ROIC (%)	-39.8	-49.1	-82.2	-37.9	13.70

1. Pre non-recurring items and post preference dividends

year to Jun, fully diluted

Accounting standard: IFRS

Source: Company data, RBS forecasts

Positive trial of afamelanotide to decrease side-effects of cancer therapy

CUV announced it had obtained positive results from a Phase II trial evaluating the photoprotective effect of its product, afamelanotide, in 16 patients who have the potential for phototoxicity (ie, sensitivity to UV light, which may lead to second degree burns) as a side-effect of cancer therapy. A significant improvement in quality of life assessment was demonstrated at 60 days of treatment (p=0.02). No significant adverse events were reported.

Afamelanotide may be used as an adjunct to cancer therapy

Some solid organ cancers have been shown to be sensitive to systemic photodynamic therapy (PDT). However, this has the effect of increase a patient's sensitivity to UV light, meaning they cannot go into sunlight without risking serious burns and pain. With these positive results, afamelanotide may eventually become the standard of care as an adjunct to some cancer treatments. We estimate more than 250,000 people in the EU and US would benefit from afamelanotide treatment to decrease the side-effects of PDT.

Second recent piece of news for CUV

This follows a recent announcement that CUV has obtained the EMEA status of small and medium enterprise. CUV will benefit from a 90% fee reduction during the centralised procedure and GMP inspection fees for final product. Clinuvel intends to file for registration of afamelanotide in Europe, Norway, Iceland and Liechtenstein in 2010.

FY10 – there is still lots to look out for

This news is in line with our forecasts. CUV should receive final results from its Phase III erythropoietic protoporphyria (EPP) trial by end 4QCY09 and, subject to the successful completion of this trial, will 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 three to nine months after filing in the US and EU.

Important disclosures can be found in the Disclosures Appendix.

Proving it up

CUV announced it had obtained positive results from a randomised placebo-controlled Phase II trial evaluating the photoprotective effect of its product, afamelanotide, in 16 patients who have the potential for phototoxicity (ie, sensitivity to UV light, which may lead to second degree burns) as a side-effect of cancer therapy. A significant improvement in quality of life assessment was demonstrated at 60 days of treatment (p=0.02). No significant drug-related adverse events were reported.

FY10 – there continues to be lots to look out for

In addition, CUV should release results of its first EU and Australian Phase III clinical trial of afamelanotide in erythropoietic protoporphyria (EPP) by end 4QCY09. EPP is a rare metabolic disorder causing severe phototoxicity. The multicentre trial is Clinuvel's second Phase III clinical trial to test afamelanotide in EPP and will further evaluate the reduction in the severity of phototoxic reactions. Pending results, the regulatory submission for marketing authorisation in the EU will follow shortly afterwards. We present an updated timeline for CUV's clinical trials and approvals in the table that follows.

Table 1 : CUV – updated timeline for clinical trials and approvals

Date (CY)	Date (FY)	Trial	RBS comment
End 4QCY09	End 2Q10	Final result of EU/Australia Final Phase III EPP (CUV017)	Then EU regulatory review begins - likely to take three to nine months from filing date. Pending the Phase III results, filing date to be made public
End 4QCY09	End 2Q10	Interim result of interim EU Phase III PLE trial (CUV015)	Should provide insight into PLE clinical response
End 2QCY10	End 4Q10	Initiate Phase III EPP trial in US (pending FDA approval, CUV030)	Trial should be complete in six months
End 2QCY10	End 4Q10	Initiate Phase III SU trial in EU (CUV023)	Trial should be complete in four months
End 2QCY10	End 4Q10	Final result 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	Start EU revenues 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 revenues from EPP
4QCY10 to end 1QCY11	2Q11 to end 3Q11	Interim results Phase II AK/SCC in OTR (CUV011)	CUV to then evaluate results and determine whether to progress to Phase III

As at end August 2009.
Source: Company data, RBS estimates

Analysis of market segments

We believe there are a number of potential market segments for afamelanotide should it get to market, including 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: RBS 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). We estimate about 2,200 sufferers in the US and EU would benefit from afamelanotide 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 (PLE)

We believe the PLE 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 PLE 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 PLE 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 PLE 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) 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.

4) 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 in the next table. We estimate more than 250,000 people would benefit from afamelanotide 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: RBS, PubMed, UN data

Target price and risks

We have not changed our earnings forecasts as this news is in line with our expectations. We believe cash flow from sales is likely for CUV sooner than for most other biotechs, and therefore that CUV warrants a premium to other biotech companies in the Australian market. Upside risks to our target price 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.

CUV – financial summary

Year to 30 Jun (A\$m)	AIFRS 2008A	AIFRS 2009A	AIFRS 2010F	AIFRS 2011F	AIFRS 2012F	Closing price (A\$)	0.29	Price target (A\$)	0.85	
Income statement						Valuation metrics				
Divisional sales	0.0	0.0	0.0	14.6	30.3	Preferred methodology	DCF	Val'n (A\$)	\$ 0.85	
Total revenue	0.0	0.0	0.0	14.6	30.3	DCF valuation inputs				
EBITDA	-17.1	-17.4	-17.9	-8.0	2.9	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	-0.1	-0.1	-0.1	Beta	1.50	Kd	8.50%	
EBITA	-17.9	-18.3	-18.0	-8.1	2.9	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)	236.0	
EBIT	-17.9	-18.3	-18.0	-8.1	2.9	Equity (E/EV)	100.0%	Minority interest (A\$m)	0.0	
EBIT(incl associate profit)	-17.9	-18.3	-18.0	-8.1	2.9	Debt (D/EV)	0.0%	Net debt (A\$m)	-21.7	
Net interest expense	4.3	2.7	3.8	2.7	2.9	Interest rate	8.50%	Investments (A\$m)	0.0	
Pre-tax profit	-13.6	-15.6	-14.3	-5.4	5.8	Tax rate (t)	30.0%	Equity market value (A\$m)	257.7	
Income tax expense	0.0	0.0	0.0	0.0	-1.7	WACC	13.2%	Diluted no. of shares (m)	303.1	
After-tax profit	-13.6	-15.6	-14.3	-5.4	4.1			DCF valuation (A\$)	0.85	
Minority interests	0.0	0.0	0.0	0.0	0.0					
NPAT pre significant items	-13.6	-15.6	-14.3	-5.4	4.1	Multiples	2009A	2010F	2011F	2012F
Significant items	-1.0	0.0	0.0	0.0	0.0	Enterprise value (A\$m)	66.2	80.1	85.2	75.8
Reported NPAT	-14.7	-15.6	-14.3	-5.4	4.1	EV/Sales (x)			5.8	2.5
						EV/EBITDA (x)	-3.8	-4.5	-10.6	25.8
Cash flow statement	2008A	2009A	2010F	2011F	2012F	EV/EBIT (x)	-3.6	-4.4	-10.5	26.6
EBITDA	-17.1	-17.4	-17.9	-8.0	2.9	PE (normalised) (x)	-5.6	-6.2	-16.2	21.7
Change in working capital	0.0	1.8	0.4	0.5	5.4	PEG (normalised) (x)				
Net interest (pd)/rec	4.0	2.9	3.8	2.7	2.9	At target price	2009A	2010F	2011F	2012F
Taxes paid	0.3	0.2	0.0	0.0	-1.7	EV/EBITDA (x)	-13.5	-13.9	-31.7	83.6
Other oper cash items	5.6	1.5	0.0	0.0	0.0	PE (normalised) (x)	-16.5	-18.1	-47.5	63.6
Cash flow from ops (1)	-7.2	-11.0	-13.8	-4.9	9.6	Comparable company data (x)	2010F	2011F	2012F	
Capex (2)	-0.2	0.0	-0.2	-0.2	-0.2	Alchemia	EV/EBITDA	-33.3	10.5	4.5
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0	Year to 30 Jun	EV/EBIT	-22.3	13.0	5.1
Other investing cash flow	0.0	0.0	0.0	0.0	0.0		PE	-26.2	13.1	6.1
Cash flow from invest (3)	-0.2	0.0	-0.2	-0.2	-0.2		PEG	-7.5	3.7	1.8
Incr/(decr) in equity	0.0	0.1	0.0	0.0	0.0	Mesoblast	EV/EBITDA	-15.7	-13.5	51.7
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0	Year to 30 Jun	EV/EBIT	-15.5	-13.5	89.7
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0		PE	-14.6	-15.2	-2351.9
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0		PEG			
Other financing cash flow	-0.5	6.6	0.0	0.0	0.0	Per share data	2009A	2010F	2011F	2012F
Cash flow from fin (5)	-0.5	6.7	0.0	0.0	0.0	No. shares	303.1	303.1	303.1	303.1
Forex and disc ops (6)	0.0	0.3	0.0	0.0	0.0	EPS (cps)	-5.1	-4.7	-1.8	1.3
Inc/(decr) cash (1+3+5+6)	-7.9	-4.0	-13.9	-5.1	9.4	EPS (normalised) (c)	-5.1	-4.7	-1.8	1.3
Equity FCF (1+2+4)	-7.4	-11.0	-13.9	-5.1	9.4	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	2008A	2009A	2010F	2011F	2012F	Dividend yield (%)	0.0	0.0	0.0	0.0
Cash & deposits	25.8	21.7	7.8	2.7	12.1	Growth ratios	2009A	2010F	2011F	2012F
Trade debtors	0.6	0.2	0.2	0.3	0.5	Sales growth	na	na	na	na
Inventory	0.0	0.0	0.0	0.0	0.0	Operating cost growth	na	na	na	na
Investments	0.0	0.0	0.0	0.0	0.0	EBITDA growth	na	na	na	na
Goodwill	0.0	0.0	0.0	0.0	0.0	EBIT growth	na	na	na	na
Other intangible assets	1.4	0.7	0.7	0.7	0.7	Norm. NPAT growth	na	na	na	na
Fixed assets	0.4	0.4	0.4	0.5	0.6	Norm. EPS growth	na	na	na	na
Other assets	26.8	18.7	18.7	18.7	18.7	Operating performance	2009A	2010F	2011F	2012F
Total assets	55.0	41.6	27.8	22.8	32.6	Asset turnover (%)	0.0	0.0	14.4	27.4
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	EBITDA margin (%)	na	na	-55.1	9.7
Trade payables	3.0	4.4	4.8	5.3	11.0	EBIT margin (%)	na	na	-55.6	9.4
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	Net profit margin (%)	na	na	-37.2	13.4
Provisions	0.0	0.0	0.0	0.0	0.0	Return on net assets (%)	-49.3	-79.0	-46.7	13.3
Other liabilities	0.2	0.2	0.2	0.2	0.2	Net debt (A\$m)	-21.7	-7.8	-2.7	-12.1
Total liabilities	3.2	4.6	5.0	5.5	11.2	Net debt/equity (%)	-58.6	-34.2	-15.8	-56.6
Preference shares						Net interest/EBIT cover (x)	6.9	4.8	3.0	-1.0
Hybrid equity						ROIC (%)	-49.1	-82.2	-37.9	13.7
Share capital	113.2	113.2	113.2	113.2	113.2	Internal liquidity	2009A	2010F	2011F	2012F
Other reserves	1.8	2.2	2.2	2.2	2.2	Current ratio (x)	8.9	5.4	4.0	2.8
Retained earnings	-63.2	-78.3	-92.6	-98.0	-94.0	Receivables turnover (x)	na	0.0	59.7	76.9
Other equity	0.0	0.0	0.0	0.0	0.0	Payables turnover (x)	na	3.9	4.5	3.4
Total equity	51.8	37.1	22.8	17.4	21.4					
Minority interest	0.0	0.0	0.0	0.0	0.0					
Total shareholders' equity	51.8	37.1	22.8	17.4	21.4					
Total liabilities & SE	55.0	41.6	27.8	22.8	32.6					

Source: RBS 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-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 09 Dec 2009)		
	Global total (IB%)	Asia Pacific total (IB%)
Buy	614 (10)	398 (1)
Add	0 (0)	0 (0)
Hold	404 (6)	223 (0)
Reduce	0 (0)	0 (0)
Sell	115 (0)	72 (0)
Total (IB%)	1133 (7)	693 (0)

Source: ABN AMRO

Trading recommendations (as at 09 Dec 2009)		
	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	6 (0)	6 (0)
Trading Sell	1 (0)	1 (0)
Total (IB%)	7 (0)	7 (0)

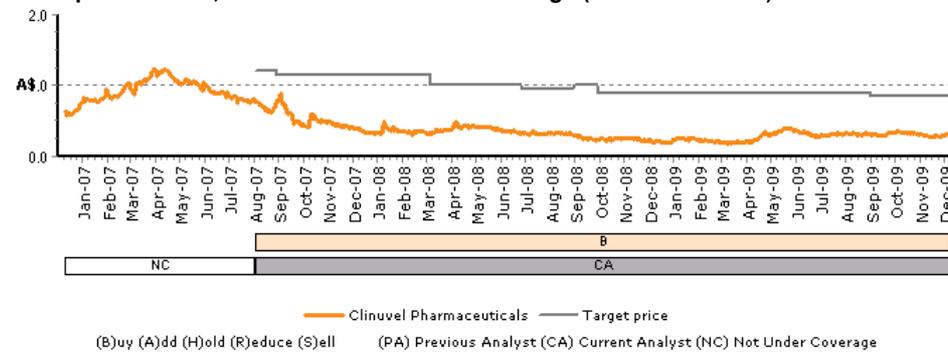
Source: ABN AMRO

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A\$0.290, TP: A\$0.85): 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 8 Dec 2009)



Trading recommendation history (as at 09 Dec 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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