Equity | Australia | Pharma & Biotech

22 December 2009

Produced by: RBS Equities (Australia) Limited

Clinuvel Pharmaceuticals

Interim Phase III results revealed

CUV announced the interim results of two Phase III clinical trials. Trials of afamelanotide yielded significant results in absolute sun allergy and non-significant results in relative sun allergy. If final the results match the interims, a positive absolute sun allergy trial result should support registration applications.

Buy

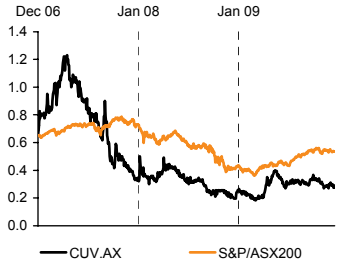
Target price
A$0.78

Price
A$0.29

Short term (0-60 days)
n/a

Price performance

	(1M)	(3M)	(12M)
Price (A$)	0.28	0.29	0.19
Absolute (%)	1.8	-1.7	48.7
Rel market (%)	2.9	-0.8	16.0
Rel sector (%)	-1.1	0.9	54.5



Market capitalisation
A$87.91m (US$77.85m)

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

RIC: CUV.AX, CUV AU
Priced at close of business 21 Dec 2009.
Source: Bloomberg

Key forecasts

	FY08A	FY09A	FY10F	FY11F	FY12F
EBITDA (A$m)	-17.1	-17.4	-17.9	-9.01	0.68
Reported net profit (A$m)	-14.7	-15.6	-14.3	-6.46	2.31
Normalised net profit (A$m)[1]	-13.6	-15.6	-14.3	-6.46	2.31
Normalised EPS (c)[1]	-4.51	-5.15	-4.70	-2.13	0.76
Normalised EPS growth (%)	21.90	14.30	-8.68	-54.7	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	38.00
EV/EBITDA (x)	n/m	n/m	n/m	n/m	116.0
Price/net oper. CF (x)	-12.2	-8.00	-6.39	-14.9	11.40
ROIC (%)	-39.8	-49.1	-82.2	-42.4	2.83

1. Pre non-recurring items and post preference dividends — year to Jun, fully diluted
Accounting standard: IFRS
Source: Company data, RBS forecasts

Statistically significant results in absolute sun allergy

CUV announced interim results of a 100-patient trial of a Phase III study of its drug, afamelanotide, in erythropoietic protoporphyria (EPP), a form of absolute sun allergy: 35 patients with severe and/or moderate pain reported the greatest reduction in the mean number of reactions (p=0.03, 95% confidence interval). Analysis of pain severity was positively correlated with treatment, indicating that patient pain scores differed significantly between treatment groups (p=0.006, 95% confidence interval).

Non-significant clinical results in relative sun allergy – larger trial planned for 2010

In addition, CUV announced trial results of a Phase III study of its drug, afamelanotide, in polymorphic light eruption (PLE). This 36-patient trial revealed a reduction in severity of symptoms in patients receiving afamelanotide compared to placebo (p=0.448 and p=0.077). In all sun-exposed areas an increase in melanin density was found at 120 days (p=0.009) and 150 days (p=0.007). Further to these results, a larger (50-patient) Phase III trial over March-October 2010 will be conducted to further delineate potential clinical responses in this patient population. Given the non-statistically significant clinical results in PLE, we will be watching for the results of a larger trial, which should be due in 4QCY10. We believe one of the potential reasons for the non-significant results could be the low sample size.

Buy recommendation and target price unchanged

In our view, the EPP trial data is positive for CUV and should support registration applications. Safety data was positive in both trials. CUV should receive final results from its Phase III EPP trial by end 4QCY09 and, subject to successful completion, 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. As a result of this news, we have not changed our forecasts.

Analysts

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Significant interim results in EPP released

CUV announced statistically significant interim results of a 100-patient trial of a Phase III study of its drug, afamelanotide, in EPP, a form of absolute sun allergy. In our view, the EPP trial data is positive for CUV and should support registration. Safety data was positive in both trials.

CUV should receive final results from its Phase III 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. 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)	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 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 December 21, 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. Next 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 and 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) EPP – absolute sun allergy; and 2) 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 treatment for EPP.

CEP is a 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 and 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 believe cash flow from sales is likely for CUV sooner than for most other biotechs, and that CUV therefore 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	AIFRS	AIFRS	AIFRS	AIFRS
Income statement	**2008A**	**2009A**	**2010F**	**2011F**	**2012F**
Divisional sales	0.0	0.0	0.0	13.2	27.1
Total revenue	0.0	0.0	0.0	13.2	27.1
EBITDA	-17.1	-17.4	-17.9	-9.0	0.7
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation/Amortisation	-0.8	-0.8	-0.1	-0.1	-0.1
EBITA	-17.9	-18.3	-18.0	-9.1	0.6
Goodwill Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-17.9	-18.3	-18.0	-9.1	0.6
EBIT(incl associate profit)	-17.9	-18.3	-18.0	-9.1	0.6
Net interest expense	4.3	2.7	3.8	2.6	2.7
Pre-tax profit	-13.6	-15.6	-14.3	-6.5	3.3
Income tax expense	0.0	0.0	0.0	0.0	-1.0
After-tax profit	-13.6	-15.6	-14.3	-6.5	2.3
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT pre significant items	-13.6	-15.6	-14.3	-6.5	2.3
Significant items	-1.0	0.0	0.0	0.0	0.0
Reported NPAT	-14.7	-15.6	-14.3	-6.5	2.3
Cash flow statement	**2008A**	**2009A**	**2010F**	**2011F**	**2012F**
EBITDA	-17.1	-17.4	-17.9	-9.0	0.7
Change in working capital	0.0	1.8	0.4	0.5	5.3
Net interest (pd)/rec	4.0	2.9	3.8	2.6	2.7
Taxes paid	0.3	0.2	0.0	0.0	-1.0
Other oper cash items	5.6	1.5	0.0	0.0	0.0
Cash flow from ops (1)	-7.2	-11.0	-13.8	-5.9	7.7
Capex (2)	-0.2	0.0	-0.2	-0.2	-0.2
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Cash flow from invest (3)	-0.2	0.0	-0.2	-0.2	-0.2
Incr/(decr) in equity	0.0	0.1	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	-0.5	6.6	0.0	0.0	0.0
Cash flow from fin (5)	-0.5	6.7	0.0	0.0	0.0
Forex and disc ops (6)	0.0	0.3	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	-7.9	-4.0	-13.9	-6.1	7.5
Equity FCF (1+2+4)	-7.4	-11.0	-13.9	-6.1	7.5
Balance sheet	**2008A**	**2009A**	**2010F**	**2011F**	**2012F**
Cash & deposits	25.8	21.7	7.8	1.7	9.2
Trade debtors	0.6	0.2	0.2	0.3	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	1.4	0.7	0.7	0.7	0.7
Fixed assets	0.4	0.4	0.4	0.5	0.6
Other assets	26.8	18.7	18.7	18.7	18.7
Total assets	55.0	41.6	27.8	21.8	29.7
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	3.0	4.4	4.8	5.3	10.9
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	0.2	0.2	0.2	0.2	0.2
Total liabilities	3.2	4.6	5.0	5.5	11.0
Preference shares					
Hybrid equity					
Share capital	113.2	113.2	113.2	113.2	113.2
Other reserves	1.8	2.2	2.2	2.2	2.2
Retained earnings	-63.2	-78.3	-92.6	-99.1	-96.7
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	51.8	37.1	22.8	16.3	18.7
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	51.8	37.1	22.8	16.3	18.7
Total liabilities & SE	55.0	41.6	27.8	21.8	29.7

Closing price (A$)	**0.29**	**Price target (A$)**	**0.78**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$ 0.78
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$m)	214.7
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-21.7
Interest rate	8.50%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	236.5
WACC	13.2%	Diluted no. of shares (m)	303.1
		DCF valuation (A$)	**0.78**

Multiples	**2009A**	**2010F**	**2011F**	**2012F**
Enterprise value (A$m)	66.2	80.1	86.2	78.7
EV/Sales (x)			6.5	2.9
EV/EBITDA (x)	-3.8	-4.5	-9.6	116.0
EV/EBIT (x)	-3.6	-4.4	-9.5	132.8
PE (normalised) (x)	-5.6	-6.2	-13.6	38.0
PEG (normalised) (x)				

At target price	**2009A**	**2010F**	**2011F**	**2012F**
EV/EBITDA (x)	-12.3	-12.7	-26.1	335.1
PE (normalised) (x)	-15.1	-16.6	-36.6	102.2

Comparable company data (x)		**2010F**	**2011F**	**2012F**
Alchemia	EV/EBITDA	-28.5	9.0	3.7
Year to 30 Jun	EV/EBIT	-19.1	11.1	4.2
	PE	-22.6	11.3	5.3
	PEG	-6.4	3.2	1.5
Mesoblast	EV/EBITDA	-14.9	-12.8	103.0
Year to 30 Jun	EV/EBIT	-14.7	-12.7	513.6
	PE	-13.9	-14.3	-129.9
	PEG			

Per share data	**2009A**	**2010F**	**2011F**	**2012F**
No. shares	303.1	303.1	303.1	303.1
EPS (cps)	-5.1	-4.7	-2.1	0.8
EPS (normalised) (c)	-5.1	-4.7	-2.1	0.8
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	**2009A**	**2010F**	**2011F**	**2012F**
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	**2009A**	**2010F**	**2011F**	**2012F**
Asset turnover (%)	0.0	0.0	13.3	26.3
EBITDA margin (%)	na	na	-68.2	2.5
EBIT margin (%)	na	na	-68.8	2.2
Net profit margin (%)	na	na	-48.9	8.5
Return on net assets (%)	-49.3	-79.0	-55.6	3.2
Net debt (A$m)	-21.7	-7.8	-1.7	-9.2
Net debt/equity (%)	-58.6	-34.2	-10.5	-49.5
Net interest/EBIT cover (x)	6.9	4.8	3.5	-0.2
ROIC (%)	-49.1	-82.2	-42.4	2.8

Internal liquidity	**2009A**	**2010F**	**2011F**	**2012F**
Current ratio (x)	8.9	5.4	3.8	2.6
Receivables turnover (x)	na	0.0	54.0	69.3
Payables turnover (x)	na	3.9	4.4	3.3

Source: RBS 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 Mid/Small 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 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 there is an investment banking relationship.

Long term recommendations (as at 22 Dec 2009)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	619 (10)	403 (0)
Add	0 (0)	0 (0)
Hold	398 (6)	221 (0)
Reduce	0 (0)	0 (0)
Sell	110 (0)	69 (0)
Total (IB%)	1127 (7)	693 (0)

Source: ABN AMRO

Trading recommendations (as at 22 Dec 2009)

	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	5 (0)	5 (0)
Trading Sell	0 (0)	0 (0)
Total (IB%)	5 (0)	5 (0)

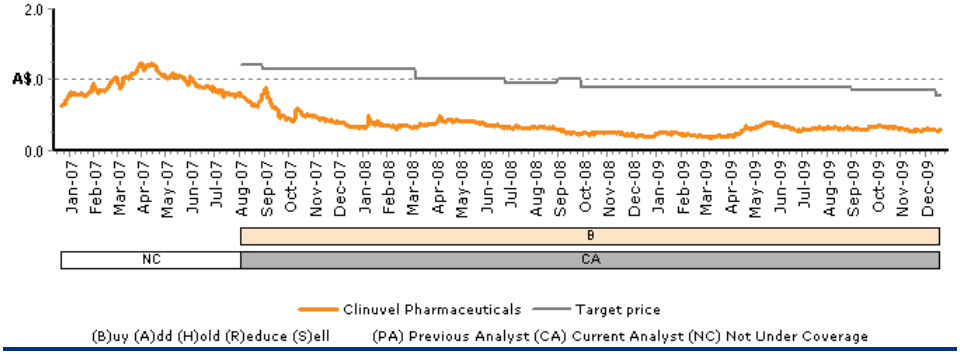
Source: ABN AMRO

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.290, TP: A$0.78): 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 21 Dec 2009)



Dr David Stanton started covering this stock on 2 Aug 07

Source: ABN AMRO

Trading recommendation history (as at 22 Dec 2009)

Date	Rec	Analyst
	n/a	

Source: ABN AMRO

Regulatory disclosures

Subject companies: **CUV.AX**

RBS is acting as sole financial adviser to StatoilHydro in the sale of Swedegas AB

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