17 December 2009

Produced by: RBS Equities (Australia) Limited

Clinuvel Pharmaceuticals

Receives orphan drug status

Afamelanotide has been granted another ODD designation in the US. This continues to send a strong signal of the medical necessity of CUV's product and removes some of the risk associated with getting afamelanotide into CUV's major potential market. Buy.

Buy

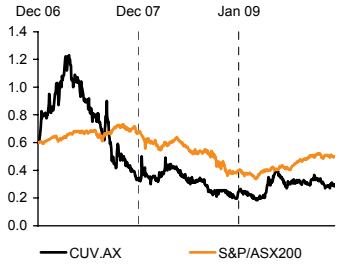
Target price
A$0.78

Price
A$0.285

Short term (0-60 days)
n/a

Price performance

	(1M)	(3M)	(12M)
Price (A$)	0.28	0.30	0.20
Absolute (%)	1.8	-5.0	39.0
Rel market (%)	3.8	-5.2	6.1
Rel sector (%)	-2.2	-3.4	37.2



Market capitalisation
A$86.40m (US$77.64m)

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

RIC: CUV.AX, CUV AU
Priced at close of business 16 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	37.30
EV/EBITDA (x)	n/m	n/m	n/m	n/m	113.8
Price/net oper. CF (x)	-12.0	-7.86	-6.28	-14.6	11.20
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

ODD is designed to address unmet medical needs

CUV's product, afamelanotide, has been granted an orphan drug designation (ODD) in the US. ODD is intended for drugs developed to prevent or treat conditions that are rare. The CUV US ODD designation for afamelanotide was granted because the drug is used to treat Solar Urticaria (SU) – a form of relative sun allergy. This gives the US Food and Drug Administration (FDA) the right to use afamelanotide in the management of Solar Urticaria, a disorder causing phototoxicity and affecting less than 200,000 patients in the US.

ODD status sends a signal of the medical necessity of CUV's product

The ODD designation has a number of benefits, including: 1) an accelerated review process by the US FDA; 2) seven-year market exclusivity in the US upon obtaining marketing authorisation; 3) tax benefits; and 4) exemption from user fees. The next major step in the regulatory process will be for final Phase III trials in SU to start in the 2010 northern hemisphere spring.

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 the EU.

Buy maintained, target price A$0.78

We believe this news is significant in that it highlights CUV's previous change in strategy to make afamelanotide a medically necessary product. Given the near-term potential cash flow from this product, we believe CUV warrants a premium compared to many other biotechs.

Important disclosures can be found in the Disclosures Appendix.

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CUV gains orphan drug status in the US

CUV's product, afamelanotide, has been granted an ODD in the US. ODD is intended for drugs developed to prevent or treat conditions that are rare. The CUV US ODD designation for afamelanotide was granted because the drug is used to treat SU – a form of relative sun allergy.

FY10 – there is still 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. The regulatory submission for marketing authorisation in the EU should follow shortly after the results of the trial. 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 16 December 2009.
Source: Company data, RBS estimates

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 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$)	**0.28**	**Price target (A$)**	**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)	64.7	78.6	84.7	77.2
EV/Sales (x)			6.4	2.8
EV/EBITDA (x)	-3.7	-4.4	-9.4	113.8
EV/EBIT (x)	-3.5	-4.4	-9.3	130.3
PE (normalised) (x)	-5.5	-6.1	-13.4	37.3
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	-27.3	8.6	3.6
Year to 30 Jun	EV/EBIT	-18.3	10.6	4.0
	PE	-21.7	10.8	5.1
	PEG	-6.2	3.1	1.5
Mesoblast	EV/EBITDA	-15.1	-13.0	104.7
Year to 30 Jun	EV/EBIT	-15.0	-13.0	522.5
	PE	-14.1	-14.5	-131.8
	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 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.

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Long Term recommendations (as at 17 Dec 2009)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	616 (10)	400 (1)
Add	0 (0)	0 (0)
Hold	401 (5)	224 (0)
Reduce	0 (0)	0 (0)
Sell	110 (0)	69 (0)
Total (IB%)	1127 (7)	693 (0)

Source: ABN AMRO

Trading recommendations (as at 17 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)

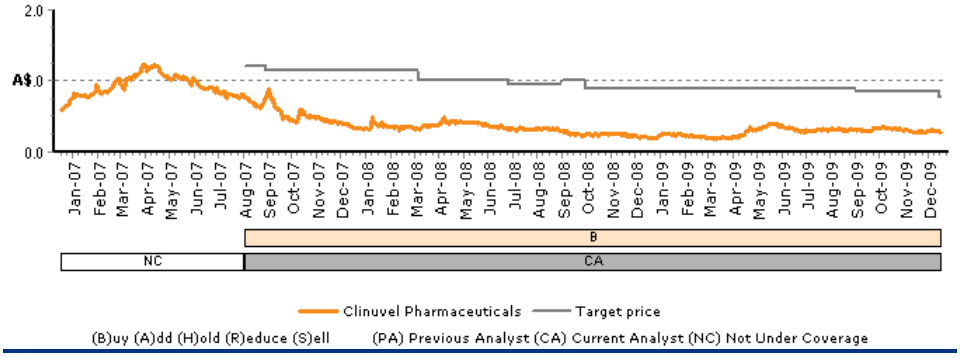
Source: ABN AMRO

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.285, 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 16 Dec 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 17 Dec 2009)

Date	Rec	Analyst
	n/a	

Source: ABN AMRO

Regulatory disclosures

Subject companies: **CUV.AX**

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