ABN·AMRO

Produced by: ABN AMRO Equities Australia Ltd

Wednesday 11 June 2008

Clinuvel Pharmaceuticals

Solar flair

CUV is to commence a Phase II trial in SU. This highlights that CUV1647 has efficacy against a number of sun-related diseases. Should the results of these trials be positive, over time we believe there is potential for large off-label use of CUV1647.

Key forecasts

	FY06A	FY07A	FY08F	FY09F	FY10F
EBITDA (A$m)	-10.3	-10.6	-15.4	-12.3	-3.22
Reported net profit (A$m)	-10.8	-9.18	-14.2	-12.2	-3.66
Normalised net profit (A$m)[1]	-10.8	-9.18	-13.5	-12.2	-3.66
Normalised EPS (c)[1]	-6.87	-3.70	-4.48	-4.05	-1.21
Normalised EPS growth (%)	-42.9	-46.2	21.3	-9.66	-70.1
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	n/m
EV/EBITDA (x)	n/m	n/m	n/m	n/m	n/m
Price/net oper. CF (x)	-4.81	-10.6	-8.62	-9.77	-50.2
ROIC (%)	-291.7	-148.4	-36.2	-30.1	-9.85

1. Pre non-recurring items and post preference dividends ***year to Jun, fully diluted***
Accounting Standard: IFRS
Source: Company data, ABN AMRO forecasts

CUV to commence Phase II trial in solar urticaria (SU)
CUV has announced that ethics approval has been granted to commence a Phase II clinical trial of its photo protective drug, CUV1647, in solar urticaria (SU). The Phase II SU trial will be conducted in Manchester, UK. Clinuvel is also in the process of obtaining approval from the relevant MECs at other trial sites in Europe (Vienna and Düsseldorf). The Manchester trial, consisting of 10 patients, will begin in 3QCY08 subject to recruiting, and is expected to complete within nine months. SU is a rare and severe, light-related skin disorder, occurring in less than 1% of the population.

CUV developing treatment against various forms of sun allergy
CUV aims to show its lead compound, CUV-1647, has efficacy against a number of sun-related diseases, including Solar Urticaria. Recently, CUV1647 was granted two OMP designations in the EU for other sun-related disorders, including: 1) erythropoietic porphyria (EPP) - absolute sun allergy; and 2) congenital erythropoietic porphyria (CEP) - a congenital form of absolute sun allergy.

Off-label use of CUV1647 possible
While we believe there is a ready market for CUV1647 in SU, EPP and EP, these markets are small. However, should the results of these trials continue to be positive, we believe that over time we will see the development of a large off-label use of CUV1647 for: 1) polymorphous light eruption (PMLE) - market size up to 100m; and 2) cosmesis - this is because one of the effects of treatment is the development of a suntan without the dangers of sun exposure. Due to the current focus of CUV on the on-label uses for CUV1647, we don't currently value its potential off-label use, but believe it could lead to material potential upside to our forecasts.

Buy maintained, target price A$1.00
We believe this news is significant in that it highlights the change in strategy to make CUV1647 a medically necessary product. Given the near-term potential cash flow, we believe CUV warrants a premium to many other biotechnology companies.

Important disclosures can be found in the Disclosures Appendix.
Priced at close of business 11 June 2008.

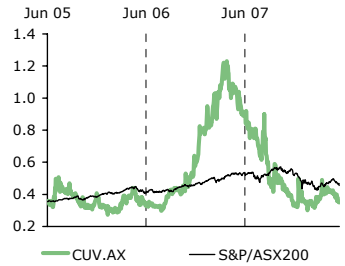
Buy

Absolute performance
n/a
Short term (0-60 days)

Pharmaceuticals & Biotechnology
Australia

Price
A$0.35
Target price
A$1.00
Market capitalisation
A$105.75m (US$100.33m)
Avg (12mth) daily turnover
A$0.23m (US$0.20m)
Reuters CUV.AX **Bloomberg** CUV AU

Price performance	(1M)	(3M)	(12M)
Price (A$)	0.41	0.33	0.93
Absolute %	-15.7	6.1	-62.4
Rel market %	-10.5	1.0	-56.9
Rel sector %	-17.2	5.9	-58.2



Stock borrowing: Easy onshore, Impossible offshore
Volatility (30-day): 55.6%
Volatility (6-month trend): ↓
52-week range: 0.93-0.30
S&P/ASX200: 5437.50
BBG AP Pharm & Biotech: 146.83
Source: ABN AMRO, Bloomberg

Analysts
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Solar flair

CUV is to commence Phase II trial in solar urticaria. This highlights that its major compound, CUV1647 has efficacy against a number of sun-related diseases. Should the results of these trials continue to be positive, we continue to believe that, over time, there will be the development of a large off-label use of CUV1647. To that end, we analyse the market segments for CUV1647, and provide an updated timeline for CUV's opportunity with CUV1647. This is shown below.

Table 1 : Timeline and probability of CUV's opportunities for CUV1647

Trial stage	Preclinical	Investigational New Drug application	Phase II trials	Clinical III trials
General time until cashflow	7 years+	5-7 years	3-5 years	1-2 years
General probability of product getting to market	c10%	c20%	c30%	c70%
Cost of trials	cA$1m	cA$2-3m	cA$10m	cA$50m
MSB products - indications and stages of development				
Polymorphous light eruption (PMLE) trial				
Erythropoietic porphyria (EPP) trial				
Skin cancer trial - all cancers apart from melanoma				
Solar urticaria (SU) trial				
Light sensitivity associated with cancer treatment				

Source: Company data, ABN AMRO estimates

Analysis of market segments

We believe there are a number of potential market segments for CUV1647 should it get to market. These include markets based on the treatment of sun allergy diseases by doctors and, subsequently, a market based on cosmetic therapy, as CUV1647 provides a sunless tan. 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 CUV1647. By our estimates, the size for the four markets we have characterised is more than 100m in the EU and US alone. We believe the majority of the patients in these markets would require treatment once or twice a year.

Table 2 : Market size EU and US – on label use of CUV1647

Disease	Prevalence in population	Implied no. patients 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. PMLE

We believe the PMLE market will be centred on doctors. This is due to the requirement for CUV1647 to be administered as a depot injection, which is generally performed by doctors.

Discussions with industry contacts suggest that 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 the diagnosis and treatment of PMLE could be made at the GP level.

However, for both patients and GPs to be made aware of PMLE as a clinical entity, we believe there needs to be an education campaign aimed at both potential patients and GPs. This would have the effect of increasing the awareness of PMLE and other sun allergy diseases as clinical entity. Given the cost of a large marketing campaign,

we believe CUV may ultimately co-ordinate a marketing campaign through a global partner, who may take a share of royalties.

2. 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.

Discussions with industry contacts suggest that SU 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.

3. Cosmetic market – off-label use

Over the longer term, we believe there is a strong chance of an off-label cosmetic market being developed for CUV1647. This is because one of the effects of treatment is the development of a suntan without being in the sun. We believe this desirable among some sectors of the community, and is only increasing. For instance, there has been a 319% increase in the number of *Yellow Pages* 'solarium' listings in Australian capital cities in the past decade. This is shown below, and suggests to us that a product that promises a tan without the risk of skin cancer would be attractive to some members of the community.

Table 3 : Solarium/tanning centre Yellow Pages listings by Aust capital city

State	Number listed in 1996	Number listed in 2006	% increase since 1996
Melbourne	25	169	576%
Perth	5	55	1000%
Canberra	4	21	425%
Adelaide	12	39	225%
Brisbane	15	47	213%
Sydney	29	63	117%
Hobart	7	12	71%
Northern Territory	0	0	na
All capital cities	**97**	**406**	**319%**

Source: ABN AMRO, Victorian Cancer Council

By our estimates, if we assume one in 100 individuals would be willing to use CUV1647 instead of attending a tanning salon, the market size for the off-label tanning market that we have been able to characterise would be in the order of more than 7.8m in the EU and US alone.

Table 4 : Market size EU and US – off label use of CUV1647

Type of use of CUV1647	Reason for use	Prevalence in population	Implied no. patients EU & US (000)
Off-label use	Tanning	1 in 100	7,850

Source: ABN AMRO estimates

In addition, we believe the off-label use of CUV1647 is only likely to increase, as the link between tanning and skin cancer becomes more apparent and better publicised.

Buy recommendation maintained, target price A$1.00

We believe this news is significant in that is highlights the change in strategy of management to make CUV1647 a medically necessary product. We use DCF valuation to derive our valuation and target price for CUV. Our valuation for CUV remains A$1.00 per share.

Upside risks include the faster-than-expected progression to production of CUV's photo-protective technology, while downside risks include any delay or failure to progress clinical trials.

On an industry-wide basis, the chances of getting a product to market from the Phase III stage are in the order of 70%. CUV management will need to balance the use of funds to progress a number of projects through regulatory pathways against the increased cash flow that this would entail. Hence, we believe CUV is an investment opportunity for investors with a higher-risk appetite.

CUV – financial summary

Year to 30 Jun (A$m)	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS
Income statement	**2005A**	**2006A**	**2007F**	**2008F**	**2009F**
Divisional sales	0.0	0.0	0.0	0.0	0.0
Total revenue	0.1	0.8	0.3	0.4	0.5
EBITDA	-11.6	-10.3	-10.6	-15.4	-12.3
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation/Amortisation	-0.8	-0.9	-0.8	-0.9	-0.9
EBITA	-12.4	-11.2	-11.4	-16.3	-13.2
Goodwill Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-12.4	-11.2	-11.4	-16.3	-13.2
EBIT(incl associate profit)	-12.4	-11.2	-11.4	-16.3	-13.2
Net interest expense	0.5	0.4	2.2	2.8	0.9
Pre-tax profit	-12.0	-10.8	-9.2	-13.5	-12.2
Income tax expense	0.0	0.0	0.0	0.0	0.0
After-tax profit	-12.0	-10.8	-9.2	-13.5	-12.2
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT pre significant items	-12.0	-10.8	-9.2	-13.5	-12.2
Significant items	0.0	0.0	0.0	-0.7	0.0
Reported NPAT	-12.0	-10.8	-9.2	-14.2	-12.2
Cash flow statement	**2005A**	**2006A**	**2007F**	**2008F**	**2009F**
EBITDA	-11.6	-10.3	-10.6	-15.4	-12.3
Change in working capital	0.0	0.0	0.0	0.4	0.5
Net interest (pd)/rec	0.5	0.4	2.0	2.8	0.9
Taxes paid	0.5	0.5	0.4	0.0	0.0
Other oper cash items	1.4	-2.0	0.0	0.0	0.0
Cash flow from ops (1)	-9.2	-11.4	-8.2	-12.3	-10.8
Capex (2)	-0.2	0.0	-0.2	-0.1	-0.2
Disposals/(acquisitions)	-0.9	-2.3	-26.7	-0.3	-0.3
Other investing cash flow	0.0	0.0	0.4	0.0	0.0
Cash flow from invest (3)	-1.1	-2.4	-26.5	-0.4	-0.4
Incr/(decr) in equity	10.2	18.3	60.0	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	-0.7	0.0	0.0	0.0
Cash flow from fin (5)	9.6	17.6	60.0	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)	-0.7	3.8	25.4	-12.7	-11.2
Equity FCF (1+2+4)	-9.4	-11.4	-8.4	-12.4	-11.0
Balance sheet	**2005A**	**2006A**	**2007F**	**2008F**	**2009F**
Cash & deposits	4.8	8.6	33.8	21.2	9.9
Trade debtors	0.1	0.2	0.2	0.3	0.3
Inventory	0.0	0.6	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	4.6	2.9	2.2	1.6	1.1
Fixed assets	0.2	0.2	0.3	0.4	0.5
Other assets	0.3	4.5	31.2	31.2	31.2
Total assets	10.1	17.1	67.8	54.7	43.1
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	2.5	3.0	2.3	2.8	3.3
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	0.1	0.1	0.1	0.1
Total liabilities	2.6	3.1	2.4	2.9	3.5
Preference shares					
Hybrid equity					
Share capital	35.1	52.7	112.8	112.8	112.8
Other reserves	1.5	1.2	1.6	1.6	1.6
Retained earnings	-29.2	-39.9	-49.1	-62.6	-74.8
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	7.5	14.0	65.4	51.8	39.6
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	7.5	14.0	65.4	51.8	39.6
Total liabilities & SE	10.1	17.1	67.8	54.7	43.1

Closing price (A$)	**0.35**	**Price target (A$)**	**1.00**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$ 1.06
DCF valuation inputs			
Rf	6.25%	10-year rate	6.25%
Rm-Rf	4.50%	Margin	2.0%
Beta	1.50	Kd	8.25%
CAPM (Rf+Beta(Rm-Rf))	13.0%	Ke	13.0%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	255.5
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-8.6
Interest rate	8.25%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	264.1
WACC	13.0%	Diluted no. of shares (m)	248.2
		DCF valuation (A$)	**1.06**

Multiples	**2006A**	**2007F**	**2008F**	**2009F**
Enterprise value (A$m)	97.1	71.9	84.6	95.8
EV/Sales (x)				
EV/EBITDA (x)	-9.4	-6.8	-5.5	-7.8
EV/EBIT (x)	-8.7	-6.3	-5.2	-7.3
PE (normalised) (x)	-5.1	-9.5	-7.8	-8.6
PEG (normalised) (x)				
At target price	**2006A**	**2007F**	**2008F**	**2009F**
EV/EBITDA (x)	-28.5	-25.3	-18.2	-23.8
PE (normalised) (x)	-14.6	-27.1	-22.3	-24.7

Comparable company data (x)		**2007F**	**2008F**	**2009F**
Alchemia	EV/EBITDA	-4.4	-4.5	-35.5
Year to 30 Jun	EV/EBIT	-3.8	-3.9	-15.1
	PE	-4.1	-4.7	-21.5
	PEG	-1.2	-1.4	-6.2
Mesoblast	EV/EBITDA	-11.8	-10.5	-8.7
Year to 30 Jun	EV/EBIT	-11.7	-10.4	-8.7
	PE	-11.9	-10.1	-11.6
	PEG			

Per share data	**2006A**	**2007F**	**2008F**	**2009F**
No. shares	185.0	302.1	302.1	302.1
EPS (cps)	-6.9	-3.7	-4.7	-4.0
EPS (normalised) (c)	-6.9	-3.7	-4.5	-4.0
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	**2006A**	**2007F**	**2008F**	**2009F**
Sales growth	na	na	na	na
Operating cost growth	-11.3%	2.8%	45.7%	-20.5%
EBITDA growth	-11.3%	2.8%	45.7%	-20.5%
EBIT growth	-9.8%	1.8%	42.7%	-19.2%
Norm. NPAT growth	-10.0%	-14.8%	47.6%	-9.7%
Norm. EPS growth	-42.9%	-46.2%	21.3%	-9.7%
Operating performance	**2006A**	**2007F**	**2008F**	**2009F**
Asset turnover (%)	0.0	0.0	0.0	0.0
EBITDA margin (%)	na	na	na	na
EBIT margin (%)	na	na	na	na
Net profit margin (%)	na	na	na	na
Return on net assets (%)	-80.2	-17.5	-31.4	-33.2
Net debt (A$m)	-8.6	-33.8	-21.2	-9.9
Net debt/equity (%)	-61.5	-51.8	-40.8	-25.1
Net interest/EBIT cover (x)	25.1	5.1	5.9	14.1
ROIC (%)	-291.7	-148.4	-36.2	-30.1
Internal liquidity	**2006A**	**2007F**	**2008F**	**2009F**
Current ratio (x)	4.5	26.9	18.2	12.0
Receivables turnover (x)	na	0.0	0.0	0.0
Payables turnover (x)	na	4.0	6.1	4.0

Source: Company data, ABN AMRO estimates

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 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. This structure applies to research on Asian and European stocks published from 1 November 2005; on Australian stocks from 7 November 2006; on continental European small and mid cap stocks from 23 November 2006; and on Brazilian stocks from 18 June 2007.

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.

Asset allocation: The asset allocation is the responsibility of the economics team. The recommended weight (Over, Neutral and Under) for equities, cash and bonds is based on a number of metrics and does not relate to a particular size change in one variable.

Stock borrowing rating: The stock borrowing rating is the subjective view and responsibility of the ABN AMRO equity finance team: Easy implies ready availability. Moderate implies some availability. Hard implies availability is tight. Impossible implies no availability.

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 11 Jun 2008)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	564 (4)	379 (1)
Add	0 (0)	0 (0)
Hold	408 (2)	231 (0)
Reduce	0 (0)	0 (0)
Sell	89 (0)	53 (0)
Total (IB%)	**1061 (3)**	**663 (0)**

Trading recommendations (as at 11 Jun 2008)

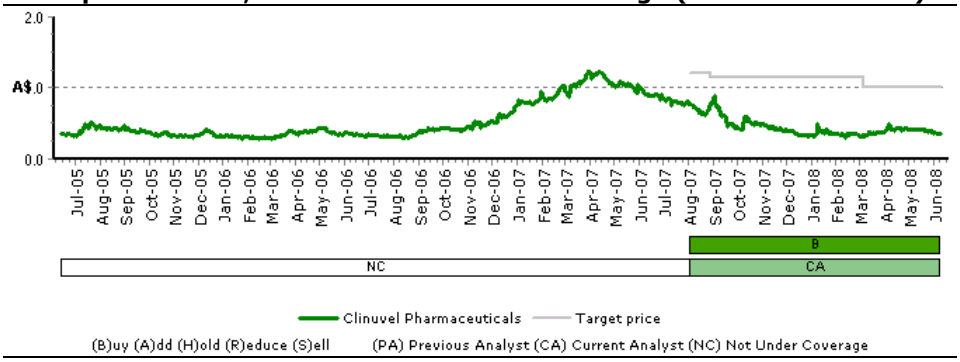
	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	6 (0)	5 (0)
Trading Sell	0 (0)	0 (0)
Total (IB%)	**6 (0)**	**5 (0)**

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.350, TP: A$1.00): 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 anti-skin allergy technology, while downside risks include any delay or failure to progress clinical trials.

Clinuvel Pharmaceuticals

Stock performance, recommendations and coverage (as at 10 Jun 2008)



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

Trading recommendation history (as at 11 Jun 2008)

Date	Rec	Analyst
	n/a	

Regulatory disclosures

Subject companies: **CUV.AX**

Global disclaimer

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