

Clinuvel Pharmaceuticals

CUV to start a new trial

CUV will start Phase II trials to test its drug CUV1647 for sun damage for immune-compromised individuals. In 1Q08, CUV had a total of A\$60.0m invested in cash/liquid financial instruments, which is in line with our forecasts. Buy.

Key forecasts

	FY06A	FY07A	FY08F	FY09F	FY10F
EBITDA (A\$m)	-10.3	-10.6	-14.4	-12.3	-2.49
Reported net profit (A\$m)	-10.8	-9.18	-13.6	-12.2	-2.91
Normalised net profit (A\$m) ¹	-10.8	-9.18	-13.6	-12.2	-2.91
Normalised EPS (c) ¹	-6.87	-3.70	-4.52	-4.05	-0.96
Normalised EPS growth (%)	-42.9	-46.2	22.2	-10.3	-76.2
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)	-6.87	-15.2	-12.2 ▼	-13.9 ▼	-111.2 ▼
ROIC (%)	-291.7	-148.4	-33.9	-30.1	-8.13

1. Pre-goodwill amortisation and exceptional items

Accounting Standard: IFRS

Source: Company data, ABN AMRO forecasts

year to Jun, fully diluted

Skin cancer trial in immune-compromised patients to start immediately

CUV will start Phase II trials to test its drug CUV1647 as a preventative for sun damage and actinic keratosis (AK), which are precursors to some skin cancers. This will evaluate the drug's ability to reduce the incidence of AK and skin damage in immune-compromised organ-transplant patients. Fair skinned patients with organ transplants are 65-100 times more likely to subsequently contract skin cancers because of the side effects of life-long administration of immune-suppressive drugs. The trial is expected to take two years, and its timing is in line with our forecasts.

This trial demonstrates further uses for CUV1647

CUV aims to show its lead compound, CUV1647, has efficacy against a number of sun-related diseases. CUV1647 induces melanogenesis, a process by which the skin's tanning cells (melanocytes) produce the skin's tanning pigment (melanin). Essentially, melanin has been shown to increase protection from the sun and decrease the ageing effects of the sun. CUV1647 stimulates the melanocytes to create a tan without exposure to damaging levels of UV radiation.

Quarterly update – status quo

In its 1QFY08 announcement, CUV released a brief report on cashflow. Net operating cashflow for 1Q08 was (A\$1.83m). This compares favourably to our FY08F forecast of (A\$14.0m), demonstrating slower-than-expected cash burn in 1Q08. We believe the rate of cash burn will increase as the company further enters Phase III trials. Also, in 1Q08 CUV invested A\$22.0m of its cash into liquid long term financial instruments (which includes hybrids). In 1Q08, CUV had a total of A\$60.0m invested in cash and liquid long term financial instruments, which is in line with our forecasts.

Our valuation and 12-month target price for CUV remains at A\$1.15

We have not changed our forecasts after the quarterly update. CUV has two trials in Phase III, with interim results expected in 2HCY08. It now also has one trial in Phase II. Given the near-term potential cash flow, we believe this warrants a premium compared to many other biotechnology companies.

Important disclosures can be found in the Disclosures Appendix.

Priced at close of business 1 November 2007.

Buy

Absolute performance

n/a

Short term (0-60 days)

Pharmaceuticals & Biotechnology
Australia

Price

A\$0.50

Target price

A\$1.15

Market capitalisation

A\$151.07m (US\$139.44m)

Avg (12mth) daily turnover

A\$0.43m (US\$0.35m)

Reuters

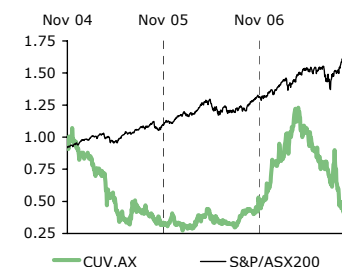
CUV.AX

Bloomberg

CUV AU

Price performance (1M) (3M) (12M)

Price (A\$)	0.4	0.8	0.5
Absolute %	11.1	-34.6	9.9
Rel market %	8.0	-40.5	-12.4
Rel sector %	17.0	-35.9	8.7



Stock borrowing: Easy onshore,

Impossible offshore

Volatility (30-day): 92.79%

Volatility (6-month trend): ↑

52-week range: 1.40-0.40

S&P/ASX200: 6754.10

BBG AP Pharm & Biotech: 162.00

Source: ABN AMRO, Bloomberg

Analysts

Dr David Stanton

Zara Lyons

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CUV to start a new trial

The main opportunity for Clinuvel is in the development of a treatment against polymorphous light eruption. This treatment is known as CUV1647, and is administered via an injection, under the skin, of a slow-release deposit of CUV1647, with the majority of the release occurring over the first 5-10 days. CUV1647 is a synthetic analogue of alpha-melanocyte-stimulating hormone (alpha-MSH) that is usually secreted by skin cells known as keratinocytes.

CUV will start Phase II trials to test its drug CUV1647 as a preventative for sun damage and actinic keratosis (AK), which forms a precursor to some skin cancers. The trial will evaluate the drug's ability to reduce the incidence of AK and irreversible skin damage in immune compromised organ-transplant patients. Fair skinned patients who have received organ transplants are 65-100x more likely to subsequently contract skin cancers because of the side effects of critical life-long administration of immune suppressive drugs. The trial is expected to take two years.

A number of opportunities for CUV

CUV is progressing five opportunities for its CUV1647 product through Phase II and III clinical trials:

- **PMLE** – CUV started its Phase III clinical trials of CUV1647 against polymorphous light eruption (PMLE) in May 2007, and should report the results of these towards the start of 2HCY08. PMLE is an acquired disease and is the most common of the disease reactions to sunlight that have an unknown cause. PMLE is characterised by recurrent, abnormal, delayed reactions to sunlight, consisting of a number of different types of lesions on sunlight-exposed surfaces. Within any one patient, only one clinical types of lesion is consistently manifested.
- **EPP** – On 5 June 2007, Clinuvel announced the Phase III trial of CUV1647 in erythropoietic protoporphyria (EPP) had begun in Zurich, Switzerland. This Phase III multicentre study is designed to determine whether CUV1647 can reduce the number and severity of phototoxic reactions in patients with EPP. In addition, the trial will determine whether CUV1647 can increase the duration of exposure to sunlight that can be tolerated by EPP patients. The company anticipates that 50-70 EPP patients will participate in the trial with patients undergoing 12 months of treatment. The interim results are expected in mid-CY08. Applications to obtain ethics and regulatory approval are currently being prepared and submitted in a number of other trial sites across Europe and Australia. Additionally, the first Australian Phase III EPP trial is scheduled to start in the second half of 2007.
- **Skin cancer trial for organ transplant patients** – CUV is progressing a Phase II trial for those with squamous cell carcinoma (SCC) and actinic keratosis (AK), a precursor to skin cancers. Organ transplant patients with fair skin are 65-100 times more likely to develop skin cancer on prescribed immune-suppressant medication following their transplant compared to the general population. CUV is progressing a trial to see if CUV1647 is a treatment option to prevent cancers in this population. If successful, it is likely clinical trials will be initiated to determine whether CUV1647 is effective against these cancers in the general population.
- **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 has started its Phase II clinical trials of CUV1647 against this disease, and should report the results of these clinical trials toward the start of 2HCY08. Should they be positive, then Phase III trials would most likely be initiated.

- **Light sensitivity secondary to a type of cancer treatment** – Photodynamic therapy (PDT) is a form of cancer therapy. PDT uses laser, or other light sources, combined with a light sensitive drug (called a photosensitising agent) to destroy cancer cells. A significant side-effect, however, is a type of light sensitivity, a debilitating photosensitivity of skin and eyes (sunlight, as well as artificial light). Essentially, this is an induced form of erythropoietic protoporphyria (EPP). Patients suffer intense pain associated with this photosensitivity and are forced to avoid light for up to 90 days following treatment. It is anticipated that CUV1647 will be shown to prevent the phototoxicity associated with photodynamic therapy (PDT) in cancer therapy. CUV has started its Phase II clinical trials of CUV1647 against this disease, and should report the results of these towards the start of 2HCY08. If positive, Phase III trials would most likely be initiated.

CUV's opportunities and timelines are 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: ABN AMRO estimates, company data

Buy recommendation maintained; price target A\$1.15

Our DCF valuation and target price remains at A\$1.15. 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.

On an industry-wide basis, the chances of getting a product to market from the Phase III stage are in the order of 70%. As a result, we believe the odds that CUV will be able to get CUV1647 to market are better than even. 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	Closing price (A\$)	0.50	Price target (A\$)	1.15	
Income statement	2005A	2006A	2007F	2008F	2009F	Valuation metrics				
Divisional sales	0.0	0.0	0.0	0.0	0.0	Preferred methodology	DCF	Val'n (A\$)	\$ 1.15	
Total revenue	0.1	0.8	0.3	0.4	0.5	DCF valuation inputs				
EBITDA	-11.6	-10.3	-10.6	-14.4	-12.3	Rf	5.75%	10-year rate	5.75%	
Associate income	0.0	0.0	0.0	0.0	0.0	Rm-Rf	4.50%	Margin	2.0%	
Depreciation	-0.8	-0.9	-0.8	-0.9	-0.9	Beta	1.50	Kd	7.75%	
EBITA	-12.4	-11.2	-11.4	-15.3	-13.2	CAPM (Rf+Beta(Rm-Rf))	12.5%	Ke	12.5%	
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0	E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A\$m)	275.8	
EBIT	-12.4	-11.2	-11.4	-15.3	-13.2	Equity (E/EV)	100.0%	Minority interest (A\$m)	0.0	
EBIT(incl associate profit)	-12.4	-11.2	-11.4	-15.3	-13.2	Debt (D/EV)		0.0% Net debt (A\$m)	-8.6	
Net interest expense	0.5	0.4	2.2	1.6	0.9	Interest rate	7.75%	Investments (A\$m)	0.0	
Pre-tax profit	-12.0	-10.8	-9.2	-13.6	-12.2	Tax rate (t)	30.0%	Equity market value (A\$m)	284.4	
Income tax expense	0.0	0.0	0.0	0.0	0.0	WACC	12.5%	Diluted no. of shares (m)	248.2	
After-tax profit	-12.0	-10.8	-9.2	-13.6	-12.2			DCF valuation (A\$)	1.15	
Minority interests	0.0	0.0	0.0	0.0	0.0					
NPAT pre significant items	-12.0	-10.8	-9.2	-13.6	-12.2	Multiples	2006A	2007F	2008F	2009F
Significant items	0.0	0.0	0.0	0.0	0.0	Enterprise value (A\$m)	133.4	108.2	120.9	132.2
Reported NPAT	-12.0	-10.8	-9.2	-13.6	-12.2	EV/Sales (x)				
Cash flow statement	2005A	2006A	2007F	2008F	2009F	EV/EBITDA (x)				
EBITDA	-11.6	-10.3	-10.6	-14.4	-12.3	EV/EBIT (x)	-11.9	-9.5	-7.9	-10.0
Change in working capital	0.0	0.0	0.0	0.4	0.5	PE (normalised) (x)	n/m	n/m	n/m	n/m
Net interest (pd)/rec	0.5	0.4	2.0	1.6	0.9	PEG (normalised) (x)				
Taxes paid	0.5	0.5	0.4	0.0	0.0	At target price	2006A	2007F	2008F	2009F
Other oper cash items	1.4	-2.0	0.0	0.0	0.0	EV/EBITDA (x)	-32.9	-29.6	-22.6	-27.5
Cash flow from ops (1)	-9.2	-11.4	-8.2	-12.4	-10.8	PE (normalised) (x)	-16.7	-31.1	-25.5	-28.4
Capex (2)	-0.2	0.0	-0.2	-0.1	-0.2					
Disposals/(acquisitions)	-0.9	-2.3	-26.7	-0.3	-0.3	Comparable company data (x)		2007F	2008F	2009F
Other investing cash flow	0.0	0.0	0.4	0.0	0.0	Alchemia	EV/EBITDA	-8.3	-8.6	-153.2
Cash flow from invest (3)	-1.1	-2.4	-26.5	-0.4	-0.4	Year to 30 Jun	EV/EBIT	-7.2	-7.4	-36.0
Incr/(decr) in equity	10.2	18.3	60.0	0.0	0.0		PE	-7.2	-8.3	-56.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0		PEG	-2.1	-2.4	-16.0
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0	pep.ax	EV/EBITDA			
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0	Year to acl.ax	EV/EBIT			
Other financing cash flow	-0.5	-0.7	0.0	0.0	0.0		PE			
Cash flow from fin (5)	9.6	17.6	60.0	0.0	0.0		PEG			
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	-12.8	-11.2	Per share data	2006A	2007F	2008F	2009F
Equity FCF (1+2+4)	-9.4	-11.4	-8.4	-12.5	-11.0	No. shares	185.0	302.1	302.1	302.1
Balance sheet	2005A	2006A	2007F	2008F	2009F	EPS (cps)	-6.9	-3.7	-4.5	-4.1
Cash & deposits	4.8	8.6	33.8	21.1	9.8	EPS (normalised) (c)	-6.9	-3.7	-4.5	-4.1
Trade debtors	0.1	0.2	0.2	0.3	0.3	Dividend per share (c)	0.0	0.0	0.0	0.0
Inventory	0.0	0.6	0.0	0.0	0.0	Dividend payout ratio (%)	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0	Dividend yield (%)	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0	Growth ratios	2006A	2007F	2008F	2009F
Other intangible assets	4.6	2.9	2.2	1.6	1.1	Sales growth	na	na	na	na
Fixed assets	0.2	0.2	0.3	0.4	0.5	Operating cost growth	-11.3%	2.8%	36.2%	-15.0%
Other assets	0.3	4.5	31.2	31.2	31.2	EBITDA growth	-11.3%	2.8%	36.2%	-15.0%
Total assets	10.1	17.1	67.8	54.6	43.0	EBITA growth	-9.8%	1.8%	34.0%	-13.9%
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	EBIT growth	-9.8%	1.8%	34.0%	-13.9%
Trade payables	2.5	3.0	2.3	2.8	3.3	Norm. NPAT growth (pre GW)	-10.0%	-14.8%	48.7%	-10.3%
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	Norm. NPAT growth	-10.0%	-14.8%	48.7%	-10.3%
Provisions	0.0	0.0	0.0	0.0	0.0	Norm. EPS growth (pre GW)	-42.9%	-46.2%	22.2%	-10.3%
Other liabilities	0.1	0.1	0.1	0.1	0.1	Norm. EPS growth	-42.9%	-46.2%	22.2%	-10.3%
Total liabilities	2.6	3.1	2.4	2.9	3.5	Operating performance	2006A	2007F	2008F	2009F
Preference shares						Asset turnover (%)	0.0	0.0	0.0	0.0
Hybrid equity						EBITDA margin (%)	na	na	na	na
Share capital	35.1	52.7	112.8	112.8	112.8	EBIT margin (%)	na	na	na	na
Other reserves	1.5	1.2	1.6	1.6	1.6	Net profit margin (%)	na	na	na	na
Retained earnings	-29.2	-39.9	-49.1	-62.7	-75.0	Return on net assets (%)	-80.2	-17.5	-29.6	-33.3
Other equity	0.0	0.0	0.0	0.0	0.0	Net debt (A\$m)	-8.6	-33.8	-21.1	-9.8
Total equity	7.5	14.0	65.4	51.7	39.5	Net debt/equity (%)	-61.5	-51.8	-40.7	-24.9
Minority interest	0.0	0.0	0.0	0.0	0.0	Net interest/EBIT cover (x)	25.1	5.1	9.3	14.2
Total shareholders' equity	7.5	14.0	65.4	51.7	39.5	ROIC (%)	-291.7	-148.4	-33.9	-30.1
Total liabilities & SE	10.1	17.1	67.8	54.6	43.0	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	5.7	4.0

Source: Company data, ABN AMRO estimates

DISCLOSURES APPENDIX

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. For UK small cap research a Buy/Sell implies upside/downside of 10% or more, an Add/Reduce 5-10% and a Hold less than 5%. This structure applies from 23 November 2006. For UK-based Global 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.

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 01 Nov 2007)		
	Global total (IB%)	Asia Pacific total (IB%)
Buy	593 (15)	395 (4)
Add	1 (0)	1 (0)
Hold	432 (19)	263 (4)
Reduce	0 (0)	0 (0)
Sell	85 (4)	59 (0)
Total (IB%)	1111 (16)	718 (3)

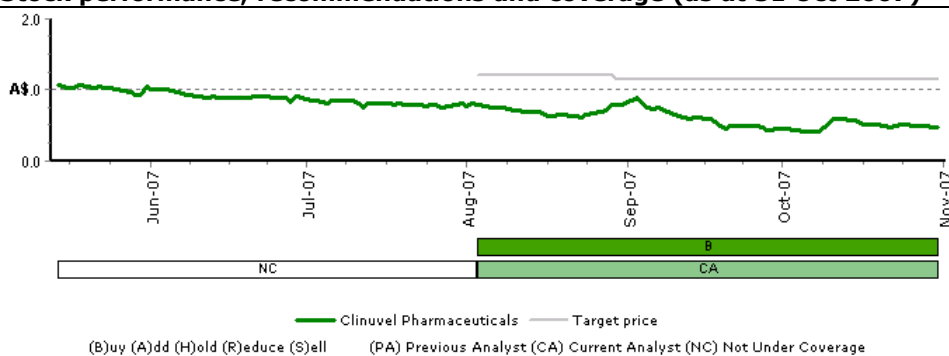
Trading recommendations (as at 01 Nov 2007)		
	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	8 (0)	6 (0)
Trading Sell	0 (0)	0 (0)
Total (IB%)	8 (0)	6 (0)

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A\$0.500, TP: A\$1.15): 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 31 Oct 2007)



Trading recommendation history (as at 01 Nov 2007)

Date	Rec	Analyst
	n/a	

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

Regulatory disclosures

Subject companies: **CUV.AX**

Global disclaimer

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