

**Clinuvel Pharmaceut. CUV**

**Friday, 31 August 2007**

***Days in the Sun to Come***

**Recommendation**

**Speculative Buy**

**12 Month Price Target**

**\$1.66**

**Clinuvel is focused on development of CUV1647**

Clinuvel is focused on development of CUV1647 ( $\alpha$ -melanocyte stimulating hormone analogue) a compound that causes pigmentation of the skin by melanogenesis, to prevent photo (sunlight)-mediated diseases.

After suffering a stock price decline from a high of \$1.40 per share to about \$0.8 per share now, an investment into Clinuvel is very attractive. The stock has declined simply due to a shift of the global perception of risk and capital to more conservative assets. Various indicators suggest that some capital is moving back into riskier assets and the biotechnology sectors would be a recipient of some of this higher risk capital. Yet we must remember that global markets are still in a time of volatility due to poor credit issues in the US, so further stock volatility is probable.

**Clinical Trials in Progress and Completed**

- One Phase III study targeting Erythropoietic Protoporphyrin (EPP), commenced in Switzerland with further sites planned in Australian and other European states. This is anticipated to be completed around March 2009. The completion of this clinical trial will be a seminal revaluation trigger for the stock. If this trial is successful, we calculated the intrinsic value of the stock to be around \$2.65 per current share.
- One Phase III study targeting Polymorphous Light Eruption (PLE), commenced in Europe, with Australian sites added around December 2007. This is anticipated to be completed around March 2009.
- Earlier Phase II trials targeting EPP and PLE were positive and indicate clinical efficacy.
- Looking forward, three Phase II Clinical Trials are anticipated to commence in 2007, which include;
  - Evaluation of melanogenesis and Actinic Keratosis / Squamous Cell Carcinoma in organ transplant patients. These patients have a higher incidence of these tumours (5% fatal) because transplant patients are on immuno-suppressive drugs to prevent organ rejection
  - Evaluation of melanogenesis and protection for patients suffering from Solar Urticaria.
  - Evaluation of protection against the side-effects of photodynamic therapy on cancer patients.

Following successful conclusion of the development programme, Clinuvel will work with global regulators to facilitate marketing approval of CUV1647.

**Recommendation**

CUV1647 is a unique and first-of-class compound, so if it gains regulatory approval, it will have the first mover advantage in photo-protective therapies. Yet, valuation of the company was problematic as there are no precedent compounds which comparable sales revenue can be used in the valuation. Therefore, the valuation was based on the average revenue and success probabilities for all classes of drugs. This represents peak sales of US\$325m on a success probability of 83%. Options Modelling estimated the value of the company at \$551m or \$1.66 per share, double the current share price. The share price is unlikely to be diluted as the company has cash reserves of about \$62m.

We recommend Clinuvel as a Speculative Buy.

**Snapshot**

Last Price	\$0.78
Market Cap (A\$m)	\$257.3m
52 Week High	\$1.40
52 Week Low	\$0.34
Sector	Biotechnology

**Investment Fundamentals**

Year-end June	HY06a	FY06a	HY07a	FY07a
NPAT (\$m)	(4.7)	(10.8)	(3.9)	(9.2)
EPS (c)	(2.8)	(6.7)	(1.8)	(3.7)
% Change	NA	NA	NA	NA
DPS (c)	0.0	0.0	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0
Yield (%)	0.0	0.0	0.0	0.0
PER (x)	NA	NA	NA	NA

Source: Historic Earnings

**Price Chart**



**Business Description**

Clinuvel Pharmaceuticals Limited (ASX:CUV, XETRA/DAX:UR9, ADR:CUVLY) strategy is to focus on clinical trials of CUV1647 to demonstrate its effectiveness in assisting to prevent UV related skin disorders.

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