

## CLINUVEL PHARMACEUTICALS (CUV)

RESEARCH



TOLHURST

Last Price	Price Target	Sector	Risk Rating	Short term <12m	Long Term >12m
\$1.04	\$1.48	Healthcare	HIGH	BUY	BUY

Company update	Company announcement
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Recommendation Change	NA
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Target Price Change	NA
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Forecast Change	NA
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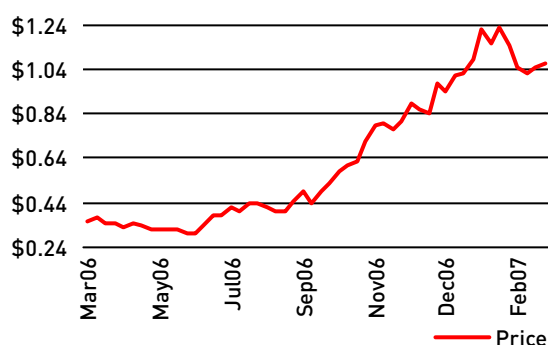
Forecast Returns	% Return- 12 months
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Forecast Price Appreciation	42.3
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Expected Dividend Yield	0.0
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Total Forecast Return	42.3
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Share Price Chart	1 Year
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## The speed of light

### Event: company announcement

Clinuvel Pharmaceuticals (CUV) announced that the Phase III trial of CUV1647 in Polymorphic Light Eruption (PLE/PMLE) has begun in Europe. The first group of patients has received either the active implant containing photo-protective CUV1647 or a placebo implant.

### Impact

This announcement is a positive step for both the company's progress towards regulatory approval for its photoprotective drug, CUV1647, in a clinical indication and for sentiment toward the share price.

The company has started 2007 at the speed of light, commencing two Phase III trials this year. No other Australian biotech can claim that. We caution that Phase III trials do carry risk.

### Response

Clinuvel is an Australian biopharmaceutical company, based in Melbourne and San Francisco, focussed on developing its leading drug candidate, photo-protective CUV1647, for a range of UV-related skin disorders resulting from exposure of the skin to the harmful effects of radiation in sunlight. Clinuvel is targeting the substantial global pharmaceutical markets resulting from increased UV radiation in the environment.

We believe CUV offers a better risk profile due to the evaluation of CUV1647's safety and efficacy in two Phase II trials, including over 300 patients.

PLE/PMLE is a common sun induced skin disorder, known as sun poisoning. It consists of an intense and persistent itchy rash with red blisters, bumps and patches on sun exposed skin. The current therapy consists of sun avoidance and/or the use of steroids and/or phototherapy. PLE/PMLE can have a significant social impact on sufferers because of their inability to go into bright sunlight in spring and summer.

Research has demonstrated that general practitioners are often unfamiliar with this disease. This fact, combined with the lack of available and efficacious treatments other than steroids, results in only a fraction of patients suffering from PLE/PMLE receiving effective treatment for their condition. Depending on the outcome of the trial, Clinuvel aims to provide sufferers with a preventative treatment for PLE/PMLE.

The first site to start the Phase III trial is Hope Hospital, Manchester, UK. The remaining trial sites across Europe are due to start administration of the implant soon. The trial will run across the 2007 and 2008 northern hemisphere spring and summer seasons and is scheduled to be completed in 2009. It is anticipated that up to 150 patients will participate. Preliminary data will be available in 12 months (Q2, 2008) with the final results in 2009.

### Valuation and Recommendation

While this arguably moves CUV one step closer along the path to market approval for CUV1647, CUV is not currently in commercialisation discussions with licensing partners. Our risk weighted valuation is unchanged.

We maintain our 'Buy' recommendation.

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### Key Points

By our reckoning this is the fourth major milestone this year to be set and met by Clinuvel MD, Philippe Wolgen, since he took over in January of 2006. This is one of five registrable clinical indications which CUV are seeking for its photoprotective drug, CUV1647.

### Surprises/Disappointments

This is a pleasant surprise. It increases the probability that an indication will obtain approval and could bring forward the timeframe for potential commercialisation, discussions with licensing partners and valuation uplift.

### Changes to Our Forecasts

There are no immediate changes to our valuation of \$1.48. We have factored in a 50% probability for Phase III success of the PMLE indication given the quantity and quality of safety and efficacy data.

### Outlook

Clinuvel has globally established a leading position in the area of UV and photo protection. With increased recognition by the public of the damaging effects of UV light and a greater awareness of the potential risk of skin cancer, Clinuvel is well poised to capitalise in this clinical area. We believe this segment will continue to grow commercially over time as increased awareness on environmental changes is of concern to impact health and well being.

### Forecast

On our probability weighted modelling CUV's target medical markets offer sales of \$1.2bn and royalty streams in the target medical market of \$87m. There is tremendous scope for future value creation typical, of the type of returns one sees from profitable specialty pharmaceutical companies with net operating margins in the 25-35% range, after 2009/10.

### Valuation

Our fully diluted NPV sum of parts analysis values the company at \$1.48 per share. This is based on DCF analysis and using probability adjusted royalty streams and a realistic discount rate of 15%, and long term foreign exchange assumptions.

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### Tolhurst's Recommendation and Risk Rating system:

Recommendations are assessments of each Tolhurst Analyst's view of potential total returns over Short Term and/or Long Term time horizons. A Short Term time horizon is less than 12 months; a Long Term time horizon is greater than 12 months.

Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into four main categories:

**Buy:** Expected Total Return more than 20%

**Accumulate:** Expected Total Return between 5% - 20%

**Hold:** Expected Total Return between -5% and 5%

**Sell:** Expected Total Return less than -5%

### Risk Ratings:

Risk is a subjective assessment of overall risk within a company including price volatility and earnings variability, external liquidity, and size.

We divide our risk into three categories:

**High:** Company typically has high price volatility and earnings variability, low external liquidity and has a small market capitalisation.

**Medium:** Company typically has moderate price volatility and earnings variability, external liquidity and a medium size market capitalisation.

**Low:** Company typically has low price volatility and earnings variability, high external liquidity and is a large size market capitalisation.

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Tolhurst may seek from the company subject to this Research Report and/or their shareholders, advisory mandates or mandates for dealings in securities, and therefore may receive commissions or fees from the companies, and/or their shareholders, at some time in the future.

In September 2006, Tolhurst accepted a mandate to act for Clinuvel in respect of a capital raising. Shares issue subsequent to the capital raising were listed on the Australian Stock Exchange on 3 November 2006. Tolhurst received fees of approximately \$205,000 some of which will be paid to its representatives. Tolhurst also participated in Clinuvel's placement in April 2007 to raise up to \$30 million for which it received a fee of up to 3% of the funds raised.

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### Analyst verification

I verify that I, Colin Mackie, have prepared this research report accurately and that any financial forecasts and recommendations that are expressed are solely my own personal opinions. In addition, I certify that no part of my compensation is or will be directly or indirectly tied to the specific recommendation or financial forecasts expressed in this report.

This report has been reviewed by peers within the research department.