

Clinuvel CUV

Short Term (<12m)

Long Term (>12m)

Last Price	Price Target	Risk Rating	Date	Sector
\$0.96	\$01.48	High	21 Feb 2007	Healthcare & Biotechnology

Strong Buy Strong Buy

Positive Phase II clinical trial results

Event

Clinuvel announced that a second Phase II clinical trial of its photo-protective drug, CUV1647, this time for EPP (Erythropoietic Protoporphria), a UV related skin condition, has met its endpoints.

Impact

This is positive news. Clinuvel will use these results to advance to Phase III for this indication as soon as possible, pending regulatory approval. We caution that Phase III trials do carry risk.

This moves Clinuvel one step closer along the path to market approval for CUV1647.

CUV are arguably also one step closer to commercialisation discussions with licensing partners and consequent valuation uplift. 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.

Overall we see this announcement as another significant positive step for the company and for the share price.

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.

EPP is currently one of four key indications that Clinuvel is investigating to pursue market approval of CUV1647. EPP is a generic condition characterised by severe light sensitivity (photo-toxicity) of the skin. The condition affects between one in 200,000 and 750,000 people. The condition mostly occurs in people with a fair skinned complexion and is characterised by excruciating pain, swelling, and scarring (mostly hands and face). The pain experienced by these patients typically requires treatment with analgesics or anti-inflammatory agents through out their lives. EPP patients are often forced to remain shielded indoors, a lifelong behaviour that gravely affects their lives.

The use of CUV1647 in the treatment of EPP could allow CUV1647 to be designated as an orphan drug which opens the path for accelerated trial path. Its severity has allowed Clinuvel to use small numbers of trial statistically significant trial results seek regulatory approval to move to Phase III.

This could potentially be Clinuvel's second Phase III trial this year.

We recommend a "Buy".

Analyst Colin Mackie

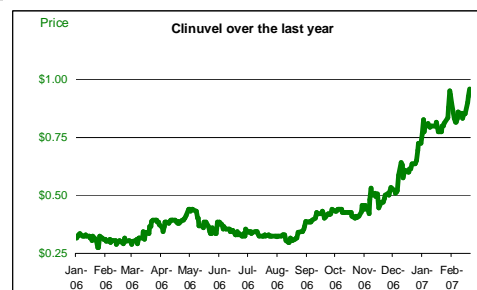
Market Stats		
Market Capitalisation	\$m	266.2
Shares Outstanding	m	277.3
12 Month Price Range	\$0.28 - \$0.97	
Monthly Turnover	\$m	5.0
Monthly Volume	m	4.5
Monthly T'over (of total)	%	11

Forecast Returns		% Return
Forecast Price Appreciation		54.2
Expected Dividend Yield		0.0
Total Forecast Return		54.2

Significant Shareholders		% Held
ANZ Nominees		28.1
Westpac Custodian Nominees		9.0
Merill Lynch		7.0
Kaupthing Bank Luxembourg		4.3

Management		Position
Roger Aston		Exec.Chair
Philippe Wolgen		MD
Dr Helmer Agersborg		Chf Sci Officer

Share Price Chart – 1 Year



Adelaide	Airlie Beach	Cairns	Geraldton	Gold Coast	Maroochydore	Melbourne	Minyama	Mt. Waverley	Perth	Sydney
08 8407 5700	07 4946 5080	07 4046 0220	08 9964 3800	07 5631 2300	07 5409 6100	03 9242 4000	07 5478 1681	03 9831 5000	08 9268 4888	02 9247 8666

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Key Points

This is the second major milestone this year to be set and met by Clinuvel MD, Philippe Wolgen, since he took over in January of 2006. This is another step closer to licensing discussions and valuation uplift. This is one of four registrable clinical indications which CUV are seeking for its photoprotective drug, CUV1647. Two indications, PMLE and EPP, may well be in Phase III trials this year.

Surprises/Disappointments

This is a very pleasant surprise. It increases the probability that an indication will obtain approval and brings 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 had already factored in a 30% probability for Phase II success of the EPP indication given the quantity and quality of safety and efficacy data.

EPP background.

EPP is a severe inherited porphyrin metabolism disorder. This disorder, known as absolute sun intolerance, causes an instant chemical known as protoporphyrin IX to accumulate in the skin. When the skin is exposed to the sun, these molecules undergo a chemical reaction that results in excruciating pain swelling, and scarring. The intolerable pain is sometimes described as like having constant boiling water or hot needles stuck into the skin. The lifelong pain experienced by these patients can be so severe that they require continuous treatment with strong analgesics to cope with the life-long pain. Typically, these patients become socially isolated because of the lack of an efficacious treatment and their need to continuously avoid sunlight and outdoors activities throughout life.

EPP market.

EPP is a generic condition characterised by severe light sensitivity (photo-toxicity) of the skin. The condition affects between one in 200,000 and 750,000 people.

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Drivers/Catalysts

Clinical milestone achievement for the following:

PMLE – approval to conduct PIII trials in 2007.

AK & SCC– approval to conduct PII / III trials in 2007.

EPP – orphan indication, seeking approval to conduct Phase III trials in 2007

SU – orphan indication, possible Phase II trial in 2007

Licensing deal indications or announcements for any of the four indications.

Outlook

Short Term

Long Term

This moves Clinuvel from being a project to being a company. The second clinical milestone has been achieved. Investor enthusiasm deserves to lift as CUV is the first Australian biotech to receive approval to conduct PIII trials in 2007.

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.

Forecasts

Short Term

Long Term

CUV's share price should lift on increased investor interest from Australia and internationally.

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

Short Term

Long Term

Our fully diluted NPV sum of parts analysis values the company at \$1.48 per share almost two times the current price. 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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Recommendation

Short Term

Long Term

Buy

Buy

Bulls Will Say

New management / clinical direction / strong funding / timeline driven / international partners = ingredients for success

Bears Will Say

The Phase III trial for this indication may yet produce an adverse result.

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In September 2006 Tolhurst accepted a mandate to act for Clinuvel in respect of a capital raising. Shares issued consequent to the capital raising, were listed on the Australian Stock Exchange on the 3rd of November 2006. Tolhurst received fees of approximately \$205,000 in respect of this mandate, some of which will be paid to its Representatives.

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Explanation of Tolhurst Noall's Recommendation and Risk Rating system:

Recommendations are assessments of each Tolhurst Noall Analyst's view of potential total returns over a 1 year period relative to the performance of the All Ordinaries Accumulation Index.

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

We have divided our recommendations into five main categories:

Strong Buy: Expected Total Return in excess of 25% over a 1 year period relative to All Ordinaries Accumulation Index

Buy: Expected Total Return between 15% and 25% over a 1 year period relative to All Ordinaries Accumulation Index

Accumulate: Expected Total Return between 5% - 15% over a 1 year period relative to All Ordinaries Accumulation Index

Hold: Expected Total Return between -5% and 5% over a 1 year period relative to All Ordinaries Accumulation Index

Sell: Expected Total Return less than -5% over a 1 year period relative to All Ordinaries Accumulation Index

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.

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.

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