Clinuvel – QuickView

5 January 2012

Event	Phase III results

Investment summary: Positive in Phase III

Positive results in the second Phase III study of Clinuvel's Scenesse (afamelanotide), a photoprotective drug for treating the orphan condition erythropoietic protoporphyria (EPP), put the drug on track for an EU approval filing, due shortly, and could be a contributory factor in the FDA's decision to conduct a Phase III trial. The data bode well for US/EU study read-outs in the potentially higher-value indication of non-segmental vitiligo (NSV), due in late 2012.

Second positive study allows filing

The 74-patient, EU Phase III study of Scenesse showed significant efficacy in its primary endpoint, pain reduction, with a median pain score of 6.0 (p=0.035). It also demonstrated a 50% reduction in phototoxic reactions (p=0.044), an increase in the time patients could experience direct sunlight without pain (p=0.005), and significant improvement in quality of life. These results pave the way for a filing with the EMA, due soon, and could be instrumental in the FDA's requirement for a Phase III.

Vitiligo indication – potentially more valuable

Confirmation of the drug's efficacy and safety profile is a step closer towards realising its potential in NSV, which has a much higher incidence than EPP. Phase II US/EU pilot studies in NSV are underway to evaluate Scenesse for the activation of melanin production in sufferers (as an adjunct to narrow-band UV light therapy), and early-stage results are due in mid to late 2012.

Well financed

Clinuvel is well financed, with end Q1 cash and short-term investments of A$14.6m. Approval of Scenesse could improve the outlook, even based on conservative estimates of market penetration, eg, a global market of c 10,000 patients, and based on the price of €32,250 per year as reimbursed under the Italian scheme.

Valuation

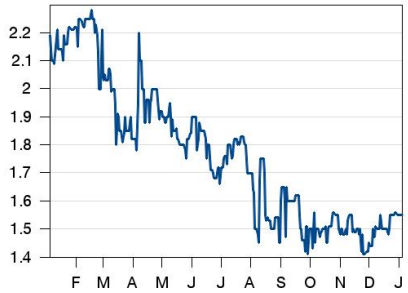
The enterprise value based on 2012e net cash of A$15m is c A$32m, which leaves potential upside on approval of Scenesse in EPP and news on the vitiligo trial.

Consensus estimates

Year end	Revenue (A$m)	PBT (A$m)	EPS (A$)	DPS (A$)	P/E (x)	Yield (%)
06/10	1.8	(11.5)	(0.38)	0.0	N/A	N/A
06/11	2.3	(11.4)	(0.37)	0.0	N/A	N/A
06/12e	2.1	(10.6)	(0.29)	0.0	N/A	N/A
06/13e	3.9	(9.2)	(0.22)	0.0	N/A	N/A

Price	A$1.55
Market cap	A$47m

Share price graph



Share details

Code	CUV/UR9
Listing	ASX/XETRA
Sector	Pharmaceuticals & biotech
Shares in issue	30.39m

Business

Clinuvel is an Australian/Swiss biotech company, principally focused on the development of afamelanotide for treating erythropoietic protoporphyria and non-segmental vitiligo.

Bull

- Near-term filing in EPP.
- Phase II US/EU pilot study in vitiligo; results due mid to late 2012.
- Strong balance sheet.

Bear

- 2025 patent expiry on drug delivery implant.
- Threat from counterfeit injectable peptides.
- Potential high price could limit market penetration.

Analysts

Robin Davison	+44 (0)20 3077 5737
Emma Ulker	+44 (0)20 3077 5738
Lala Gregorek	+44 (0)20 3077 5736

healthcare@edisoninvestmentresearch.co.uk

Edison Investment Research

Lincoln House, 296-302 High Holborn, London, WC1V 7JH ■ tel: +44 (0)20 3077 5700 ■ fax: +44 (0)20 3077 5750 ■ www.edisoninvestmentresearch.co.uk
Registered in England, number 4794244. Edison Investment Research is authorised and regulated by the Financial Services Authority.