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# Retrophin’s bid to end Clinuvel’s wilderness years

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Yesterday’s disclosure of an unsolicited takeover approach for Clinuvel is an unexpected development for the Australian biotech company, whose history has been characterised by changes of strategy and a protracted regulatory delay.

The approach by Retrophin offers either cash or stock, and values Clinuvel at A$95m ($89m). Retrophin, a young biotech run by the former fund manager Martin Shkreli, had already signalled its aim to acquire products in the rare disease space, and it clearly saw an opportunity in the target company’s woes.

Retrophin already owns 4.88% of Clinuvel, and actually made the takeover approach back on July 17, but this was not disclosed until yesterday. Clinuvel stock rose 29% today; the company issued a statement cautioning that the proposal was subject to numerous conditions, and advised investors to take no action for now.

Given Retrophin’s rare disease focus it is possible that it was drawn to Clinuvel after the Australian group received EU orphan designation in May for use of its lead project, Scenesse, in Hailey-Hailey disease, an inherited skin condition for which it is in phase II studies.

However, in its June 17 approach Retrophin said the attraction was Scenesse’s use in erythropoietic protoporphyria (EPP), a rare light intolerance disorder for which the project is awaiting EU approval. This is Scenesse's latest primary indication, but has seen Clinuvel struggle.

Despite generating positive phase III results in EPP, leading to an EU filing back in February 2012, over two years later Scenesse has still not received the regulatory green light (*Event – Scenesse waiting game could finally be over, January 16, 2013*).

**29 months and counting**

At its latest update two months ago the group said the EU regulatory review should now be completed between July and October, but cautioned that further reviews were possible. It put the delay down to the complexity of both the dossier and EPP, and said no other melanocortin had ever been filed for European approval.

Some had viewed EPP as merely a stepping stone towards getting Scenesse approved for vitiligo, or the loss of skin pigmentation – a much larger potential use. However, Retrophin clearly sees a fit for EPP in its orphan disorder focus, and it might particularly like the idea of a US FDA filing, which had been planned after the receipt of EU approval.

That said, Clinuvel’s path towards an orphan disease approval has been anything but straightforward. The company started out life as Epitan, a business based around Scenesse – then known as Melanotan – as a cosmetic product to aid tanning. It floated in Australia in 2001 and planned a London IPO four years later.

After a management change the group was renamed Clinuvel and its focus moved away from cosmetic towards medical uses of the project, which it then designated CUV1647. Cash was raised on the strength of an actinic keratosis trial, though in this indication Scenesse's development has not moved beyond phase II.

EPP, and vitiligo, emerged as potential uses after later clinical successes, though a US phase III study in EPP failed to hit its primary endpoint. Given the setbacks and changes in strategy it is unsurprising that Clinuvel’s stock has refused to do little more than tread water over the past five years.

The group’s response to Retrophin’s proposal will say a lot about how close Scenesse is to securing regulatory backing at long last.

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