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*Daily news on ASX-listed biotechnology companies*

# Dr Boreham's Crucible: Clinuvel Pharmaceuticals

By TIM BOREHAM

**ASX Code:** CUV

**Share price:** $6.90

**Market cap:** $329.4 million

**Shares on issue:** 47,735,227

**Chief executive officer:** Dr Philippe Wolgen

**Board:** Stanley McLiesh (chairman), Dr Philippe Wolgen, Brenda Shanahan, Elie Ishag, Willem Blijdorp

**Financials (2016-'17 year):** revenue $17.0 million (up 165%), maiden net profit $7.11 million (previous loss $3.15 million), cash of $23.7 million (2015-'16: $13.8 million)

Identifiable shareholders: Lagoda Investment Management 11 percent, Fidelity Investments 9.6 percent, Dr Wolgen 7.8 percent, Ender 1 LLC (Sean Parker) 4.9 percent.

Clinuvel chief Dr Philippe Wolgen describes the drug developer's journey as "counter-current to arrive at the present point" - and don't we love the former cranio-facial surgeon and enthusiastic soccer player's quaint Franco-Dutch phraseology.

“Rather than traversing along the fastest imaginable and plotted route to success, we have frequently been impelled to take tortuous avenues to achieve our objectives,” he told shareholders recently.

Unlike the majority of ASX-listed drug plays, at least Clinuvel has navigated these tortuous routes. It actually has a drug on market - to treat rare skin intolerance to sunlight - which makes the company a rarity in itself.

Revenues are flowing and last month the company posted a substantial maiden profit of $7.1 million.

**Safe tanning appeal fades**

Wolgen’s “tortuous” reference could well refer to Clinuvel’s origins as Epitan, which as the name suggests was pitching a synthetic peptide, melanotan, as a safe tanning agent.

The earnest Dr Wolgen put paid to all of that malarkey when he joined the company in 2005, although the US Food and Drug Administration had already refused approval two years earlier. Since then the company stuck to a serious clinical program for the technology, now known as Clinuvel’s lead drug Scenesse (afamelanotide).

In 2014, the European regulator approved Scenesse to treat erythropoietic protoporphyria, or EPP, an extreme sun intolerance afflicting about 5,000 people - colloquially known as shadow chasers - globally.

Strictly speaking, the drug treats the phototoxic side effects of severe burns and anaphylactoid reactions.

While it may seem odd that Clinuvel targeted such a small market, one way of looking at it is that the company is proving Scenesse with a most extreme skin condition.

Clinuvel also cites a market of 45 million people for broader target disorders such as vitiligo, the loss of pigmentation in dark-skinned people that affects about one percent of the population.

(Michael Jackson was the most famous sufferer, before he killed himself with an anaesthetic drug in a cautionary tale of off-label usage).

Scenesse is approved for EPP in Europe, with the $17 million of revenue including the first 12 months of commercial sales in the Netherlands, Italy, Austria and Germany.

The full-year revenue includes $4.83 million of revenue granted under special access schemes that recognise the rarity and untreated nature of the condition.

The UK National Institute of Health Care and Excellence (NICE) is evaluating Scenesse in terms of special availability to adult patients and reimbursement by the National Health Service.

And in April this year German insurers agreed on a reimbursement regime “aligned to the company’s uniform global pricing policy”.

Clinuvel’s clinical focus is now on a phase II, Singapore-based trial for vitiligo, “evaluating the use of Scenesse in diverse patient groups with various skin complexities”.

**Coming back for more**

In a July update, Clinuvel reported two quarters of growth for Scenesse, with 98 percent of the European EPP patients treated for the first annual cycle coming back for a second round of photo-protection.

The treatment costs about $US28,000 a year.

After the European Medicines Agency approved Scenesse in 2014, Dr Wolgen said one reason for the consent was the company’s reassurance the drug would not be used for “off label” purposes (such as safe tanning).

That was a spit-on-the-hand, Scout’s honour pledge, but it seems the regulators are a suspicious lot. “Despite our proclamations, European regulators still seek evidence and confirmation of our exclusive supply to EPP patients,” Dr Wolgen says.

“At times I have been surprised by the lack of realisation of leading regulatory authorities as to the significance of public statements made by listed companies, including Clinuvel,” he says.

We can think of a reason: a few of them elsewhere are known to stretch the truth.

**Out of the shadows**

The US market also beckons: in July last year the FDA granted Scenesse fast track approval status for EPP and subsequently accepted Clinuvel's data as adequate for a new drug application.

The FDA is happy to receive a rolling series of dossiers on how the drug is faring.

The process is helped by the real life European experience of Scenesse, with no emerging safety concerns.

In the meantime, Dr Wolgen says, US EPP patients are requesting information on the availability of the drug, which has made a profound difference to many of the patients treated.

“Knowing that there is a treatment available while not being able to obtain it must be an unspeakable frustration of many patients in the US,” Dr Wolgen says.

“The regulatory hurdles to make a novel drug available are increasingly high and the administrative processes after drug approval have become complex and time consuming,” Dr Wolgen says.

**Dr Boreham’s diagnosis:**

The commercialization of Scenesse comes after 11 years of development and 17 years as a listed entity. In drug development land, it’s a rare example of plugging away and actually getting somewhere.

Dr Wolgen, who helped bolster the share register with the addition of the likes of billionaire Napster founder Sean Parker, can take a bow.

In glorious hindsight, the board was right to snub New York’s Retrophin that lobbed a hostile $2.17 a share offer in July 2014, valuing the company at about $95 million.

The shares have traded between $1.13 and $8 over the last decade, with the company evolving from Epitan in 2000.

Clinuvel established a level 1 American depository receipt program and these days close to 12 percent of all shares on issue are held as these instruments.

The fundamental constraint of EPP is that it’s such a small market, although Scenesse reportedly has changed the lives of sufferers who need not hide in the broom cupboard on a sunny day.

While it’s too late for Michael Jackson, a vitiligo treatment would help to justify Clinuvel’s current $300 million-plus market capitalisation.

Punters should expect to hear more about from the company at its November annual general meeting when it unveils its the ‘2020 Strategy’, hopefully not the same one proposed by former Sirtex chief executive officer Gilman Wong.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. One could say his knowledge of the topic runs only skin deep.***