



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Zelira Therapeutics

By TIM BOREHAM

ASX code: ZLD; **OTCQB:** ZLDAF

Share price: 3.2 cents

Shares on issue: 972,528,406

Market capitalization: \$31.1 million

Chief executive officer: Dr Richard Hopkins

Board: Osagie Imasogie (chairman), Harry Karelis (executive deputy chairman), Dr Hopkins, Lisa Gray, Dr Oludare Odumoso (US managing director), Jason Peterson

Financials (December half 2019): income \$13,210 (down 72%), loss of \$2.6 million (previous deficit \$2.1 million), cash on hand* \$1.12 million, estimated March quarter outflows \$1.5 million

* Cash balance bolstered by \$4.64 million placement post balance date.

Major identifiable holders: Jason Peterson 7.7%, Harry Karelis 5.1%, Mara Gordon 4.5%, Stewart Washer 3.6%, Merchant Leaders Fund 3.3%, Osagie Imasogie 1.7%, Lisa Gray 1.7%.

Zelira chief Dr Richard Hopkins confirms what your columnist suspected was a self-serving myth perpetuated by overzealous users of the intoxicating herb: no one has ever been recorded as overdosing on cannabis over millennia of usage.

"The safety profile is amazing and that's the bit that everyone has forgotten," Dr Hopkins says.

He further muses that medical pot has gone from being outlawed to grudgingly accepted - and then classed as an essential service. Yes, that's right! During the Covid-19 lockdowns in the US, cannabis outlets are open as usual.

Bearing in mind that 30 to 40 percent of clinical trials are halted for safety reasons, marijuana's innocuous status** is one less hurdle to overcome as Zelira seeks to commercialize its medicinal cannabis formulation ZLT-101, for the treatment of chronic insomnia.

Last month Zelira revealed the results of a phase Ib/IIa trial that showed a "statistically significant" improvement among the 23 sleepless participants (more details below).

"Globally we are the first company to take a full spectrum cannabis product and test it for efficacy in the insomnia space," Dr Hopkins says.

"We will be one of the few cannabis companies in the world with clinical validation."

While any regulatory approval is a long way off, Zelira hopes to release the drug as an unregistered product, generating significant revenues within months.

After all, sometimes counting sheep just doesn't cut it.

From Zelda to Zelira

The Zelira moniker is an amalgam of Zelda and Ilera, which as far as concocted names go is a fairly logical and elegant one.

The California based Zelda back-door listed on the ASX on November 22, 2016, having raised \$4 million at 2.5 cents apiece. The name derived from the company's association with pot shop Aunt Zelda's, also founded by Zelda co-founder Mara Gordon.

Zelda's other founders were local biotech likely lads Harry Karelis (Titan Capital Partners), Dr Stewart Washer (lots of biotech boards) and Jason Peterson from CPS Capital.

Aimed at becoming one of the few marijuana companies with clinical validation, Zelda entered a baffling array of liaisons and collaborations. Partners include or included the listed pot stock Auscann in a joint venture in Chile; and Suda Pharmaceuticals to develop an oral mist delivery product.

In keeping with the company's Perth domicile, the local medical research house Telethon Kids Institute and Curtin University are also research partners.

Zelira also has a tie-up with the recently listed Emerald Clinics (with chairman Dr Stewart Washer), in view of accessing data for patients treated for pain and insomnia.

In May 2018, the company recruited molecular biologist Dr Richard Hopkins as CEO. Dr Hopkins formerly led the ASX listed doggie drug play Pharmaust; and previous to that led and co-founded Phylogica, with Dr Stewart Washer and Harry Karelis.

In October last year, the company announced the scrip acquisition of the Pennsylvania based Ilera, which provides over-the-counter cannabis therapies under the Hope brand.

The key here is that Ilera licences the product on a state-by-state basis and doesn't touch the stuff itself, resulting in low overheads.

Zelira has also partnered with Europe's Hapa Pharm BV to access the medical cannabis group's certified manufacturing facilities and its German distribution network.

The merger saw Ilera founders Osagie Imasogie installed as chairman, with Ilera's Lisa Gray also assuming a board seat. Mr Karelis stayed on as deputy chair, while Ms Gordon and Dr Washer resigned, with Ms Gordon remaining on the company's medical board.

Pleazzzzing trial results

Carried out at the University of Western Australia's Centre for Sleep Science, the trial registered 24 chronic insomnia patients, aged between 25 and 70 years.

The study was randomized, double-blinded and placebo controlled, with a crossover structure which involved the human guinea pigs being treated with 14 nights of ZTL-101 and 14 nights of placebo.

To further remove bias, the patients were not told the trial involved cannabis, although they were all subjected to a pre-trial test to gauge their sensitivity to the weed.

Depending on the severity of their symptoms, the 23 patients satisfying the trial protocols were administered 11.5 milligrams of total cannabinoids in 0.5 millilitre doses, or 23mg in 1.0 millilitre doses.

The description of the results descends into scientific mumbo jumbo, but the key message is that the ZTL-101 reported benefits that were only a slim chance of being a fluke (a 'p' – probability – score of less than 0.001).

The improvement was measured by a standard measure called the Insomnia Severity Index.

Interestingly, 17 of the participants reported non-serious side effects including dry mouth, headache and "feeling abnormal" (a.k.a a little bit floaty and woozy).

Intriguingly four placebo recipients also reported adverse effects including "variable mood", but perhaps they were just cross that the 'drug' wasn't working.

Dr Hopkins notes that it would be impossible to conduct such a trial in the US, because medical dope is still not legal at a Federal level.

While only 23 people, the crossover design meant it was in effect 46. "It's not so much big numbers that's important, but how the trial is powered."

What now?

Here's the size of the prize: 70 million Americans have insomnia. They're not just Sleepless in Seattle but also tossing and turning in New York and New Mexico. And the Covid-19 pandemic and panic won't be helping.

Over-the-counter insomnia treatments generate \$US2 billion of annual revenue in the US.

Dr Hopkins says the global insomnia market is worth \$US10 billion and dominated by benzodiazepines and opioids.

"We desperately need something other than these addictive drugs - and in many cases medical cannabis is an option," he says.

He cites the experience of GW Pharma which owns Epidiolex, approved by the US Food and Drug Administration for a rare form of epilepsy.

In its first nine months on market, Epidiolex generated \$US350 million of revenue.

"We have a much bigger addressable market."

The obvious question is why insomniacs won't access a joint - legal in many US states - and gently inhale themselves into a slumber, perhaps with a nip of Jack Daniels on the side?

Dr Hopkins says Zelira is targeting the tinctures and oils market which has operated differently to the recreational market, which is focused on flowers or processed derivatives of the bud.

He says "we are no threat to the recreational market" - and that means the recreational market is no threat to Zelira.

Zelira has also patented what we thought couldn't be owned: the formulation that stipulates the ratio of THC (tetrahydrocannabinol) to the cannabidiol (CBD).

Finances and performance

The Ilera merger delivers a wider portfolio of products under the Hope banner, due to hit the market this year.

Two formulations are generating revenues, but this income is yet to hit the accounts: in the December half the company reported \$13,210 of interest income and a \$2.57 million loss.

At the time the company had cash of \$1.2 million, supplemented post balance date with a \$4.64 million placement executed at five cents a share.

In early 2018, Zelda started trading on the New York OTCQB, an exchange for small caps still on trainer wheels. But Dr Hopkins says a Nasdaq listing is a “case of not if but when” - possibly in 12 months.

The Ilera purchase was satisfied by issuing 113,601,290 Zelda shares, at a nominal 5.5 cents a share.

Two tranches of performance rights (both amounting to 362,620,322 shares) are payable to Ilera’s vendors, when revenue hits \$US1 million and \$US2.5 million respectively. If these hurdles are achieved, Ilera emerges with 50 percent of the Zelira register.

After an initial flurry after the insomnia results, Zelira shares have trended downwards, having been as high as nine cents in late July 2019. The stock traded as low as 2.2 cents on March 23 – a day of overall share market horrors.

What’s next?

Beyond insomnia, Zelira is also interested in the market for post-traumatic stress disorder, autism and opioid reduction. The latter should press a few hot buttons in the US, given the country’s well-aired problems with Hillbilly Heroin (the potent prescription painkiller oxycodone).

In February, the company said it had fully enrolled a phase Ib trial of long-term opioid users. Dosing is due to be completed by April with results by mid-2020.

The trial is being conducted at St Vincent’s Hospital in Melbourne, with Emerald Clinics in Perth hosting a second site.

The dose escalation trial will focus on safety, but will also record the patients’ pain, mood, sleep and opioid usage levels.

Dr Hopkins promises two more revenue-generating products towards mid-year. “One will be oral over the counter and another one dermatological - it’s bloody exciting.”

Dr Boreham’s diagnosis

Zelira is gearing up its US adventures at a time when the FDA plans to take a long, hard look at the proliferating over-the-counter trade in unproven cannabis remedies.

At last count, medical cannabis was legal in 34 countries and 33 US states. Elsewhere, Australia, New Zealand, Britain and Germany are potential markets.

In the crowded ASX pot space, it pays to have attributes above and beyond a licence to grow the stuff and vague intentions to devise new-fangled delivery mechanisms or cannabis infused honey or beer ... or even instant tea.

The closest ASX-listed exemplar to Zelira is Medlab, which has a focus on oncology-related pain but also generates revenue from food additives here and in the US.

No fewer than 70 biotech watchers tuned into Zelira's briefing post the clinical results, which shows the audience still hankers for properly validated treatments.

There'll be quite a bit of news coming out of the Zelira camp and in the meantime the stock is a sleeper, so to speak.

** (Non) government health warning: cannabis usage may not be safe for other reasons - including accidents induced by psychosis, mental health issues, slothfulness and appetite overstimulation (also known as 'the munchies'). You wouldn't want to have to take a random drug driving test, either

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has the gift of sleep, and counting sheep - usually just one of them - does the job.