



Biotech Daily

Friday March 23, 2018

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Medlab Clinical

By **TIM BOREHAM**

ASX code: MDC

Share price: 64.5 cents; **Market cap:** \$134.2 million; **Shares on issue:** 208,021,667

Chief executive officer: Sean Hall

Board: Michael Hall (chairman), Sean Hall, Drew Townsend

Financials (December half): Revenue \$2.43 million, loss \$2.36 million, cash \$789,691, estimated current quarter cash flow \$2.5 million

Major holders: Sean Hall (Commdox) 27.04%, Michael Hall (FIT Investments, Hallab) 7.3%, Drew Townsend (Realm Group, Rolay) 7.7%, Farjoy Pty Ltd 10.12%.

What have the pot stocks been smoking?

It seems the listed medical cannabis sector has lost its way in the haze, deviating from the clinic to the easier lifestyle pickings of cannabis beer and honey, nutraceuticals and supplying recreational dope to the legal Canadian market.

One could say the sector has become somewhat dis-jointed.

These pursuits may well deliver revenue faster for investors, but the scope for growth is limited because the barriers to entry are low.

Arguably there are richer pickings for the companies that play the long game and develop clinically proven and approved drugs for which they can charge a premium.

“I question how much is pie-in-the-sky versus realistic,” Medlab chief Sean Hall says of his cannabis stock peers.

Medlab’s traditional path

The quirky aspect of Medlab is that it’s actually doing something unquirky and focusing on the market for intractable oncology pain.

Mr Hall says cancer pain presents one of the most significant unmet needs and of course many of these patients have been self-medicating on the healing herb for years.

Medlab is also targeting non-cannabis trials for obesity, diabetes and depression.

Unusually, Medlab has two cannabis products on the market: Nanabis for pain (containing the ‘whoopie’ ingredient tetrahydrocannabinol (THC) and very low THC Nanabidial for chemotherapy-induced nausea and vomiting (CINV).

Unfurling the web of regulation

In January, the Victoria Government approved Medlab to sell a Schedule 8 (controlled) or Schedule 9 (prohibited) drug.

Nationally, Medlab has approval to sell anywhere, except the traditional hold-out jurisdictions of Tasmania and the Northern Territory.

The drugs are being sold under the Australian Therapeutic Goods Administration special access scheme, which means the substances aren’t approved but can be administered under tight conditions.

Last November, the TGA granted Medlab an import licence and the company procures supply from Canada.

A contract manufacturer is already chugging out Nanabis at a Melbourne facility and Medlab had scheduled first sales by the end of February.

Approved pot drugs are few and far between.

GW Pharma’s Sativex is approved in 30 countries outside the US, but for the tight claims of multiple sclerosis spasticity rather than cancer pain.

Two other synthetic cannabis drugs have been approved. These are Marinol (loss of appetite and cancer induced pain and nausea) and Cesamet (nabilone) for CINV.

A 'potted' history

Medlab is a family affair: the Halls owns about one third of the stock.

Patriarch Michael Hall bought and sold four food additive companies, including FIT Bioceuticals that Blackmores acquired for \$40 million in 2012.

The Halls listed Medlab in July 2015 after raising \$6 million at 20 cents apiece, valuing the entity at \$14.4 million.

Initially the company focused on food additive and "probiotic" products, which it sells under names such as Multibiotic, En Biotic and NRGBiotic.

Last July, Medlab teamed with the listed "beauty and wellness" house Heritage Brands to develop "next generation" over-the-counter pharmacy lines.

Shortly after listing the company turned to cannabis (so to speak) when the New South Wales government granted a research licence.

One reason for the government's assent is that Medlab has its own certified biologics lab in Sydney.

Cannabis on trial

In June 2017, the TGA approved Medlab's proposal for a human trial, to be held at Sydney's Royal North Shore Hospital and investigating advanced cancer patients with intractable pain.

The trial, under the direction of oncologist and palliative care specialist Prof Stephen Clarke, will be the first of its kind in oncology pain, and will dose patients with Nanabis instead of opioids and is expected to start shortly.

The trial will use Medlab's patented Nanocelle, which delivers a particle mouth spray inside the cheeks.

This means the substance is delivered straight to the blood and bypasses the complications of kidney and liver function.

"We have something cleaner and more concentrated which is not diluted by the natural defence systems," Mr Hall says.

Unsurprisingly the TGA takes a sober approach to prescribing cannabis.

Smoking the stuff is definitely not preferred, while it advocates a "start low, go slow" approach.

“In populations not naive to cannabis, dosing advice should be to consider tolerance and accumulation of THC in fat stores,” the TGA says.

In other words, be careful with pothead patients already familiar with the substance.

Financially speaking

Thanks to Medlab’s behind-the-counter food additive lines, the company’s revenue is ticking over like a hydroponic dope grower’s power meter: \$2.36 million of customer receipts in the December half and \$1.18 million in the December quarter.

The cash balance looked depleted but in January it was bolstered by a placement that raised \$24 million at 90 cents apiece.

This makes the company well-placed to fund the trial.

Medlab shares peaked at \$1.12 on January 19, after the “heavily oversubscribed” raising.

Medlab has not finalized pricing for Nanabis, but indicates a cost to the patient of \$450 to \$850 a month (depending on the dosages the docs prescribe).

Medlab’s contract manufacturer in Melbourne has made 500 bottles ready to go, ramping up to 1,000. Each bottle lasts about a month.

“We are not budgeting sales,” Mr Hall says. “It’s more a test of the real world patient experience ... and the comfort level of doctors.”

To that end, Medlab has been on a roadshow to educate the docs, with around 500 turning up to jamborees in Sydney, Melbourne and Brisbane.

Approved for clinical trials, Nanabidial is expected to be nowhere near as expensive. But the regulatory path is not easy because it is still classified as cannabis and contains a small amount of THC (less than two percent).

Mr Hall believes the chemotherapy-induced nausea and vomiting market will be bigger than for cancer pain, but more crowded.

Dr Boreham’s diagnosis:

With a \$135 million market cap, Medlab is the third biggest pot stock, behind the runaway Auscann (AC8, \$461million) and Cann Group (CAN, \$426 million).

This month, Medlab joined Cann Group on the All Ordinaries index as part of the ASX’s quarterly rebalancing of its indices (not that it did much for the share price).

With the ASX pot stock population nudging 20 entrants, it's getting harder to nut out who is likely to succeed. Our guess is a minority.

It doesn't help that they all make claims to supposedly unique milestones such as first import licence, first growing licence or first sponsorship deal for the Nimbin Mardigrass or the Seattle Hempfest.

A proper clinical trial - coupled with a product already on market - is a decent starting point. That gives Medlab a "head" start.

While the instos who subscribed to the placement are under water, shareholders in the initial public offer can't complain with their investment up more than three-fold.

Winning the support of doctors is crucial. But as Australian Medical Association prez Dr Michael Gannon recently said: "show us the scientific evidence and doctors will prescribe it".

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He secretly looks forward to tasting his first cannabis beer, but promises he won't inhale.