



# Biotech Daily

Friday December 21, 2018

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 0.69 percent on Friday December 21, 2018, with the ASX200 down 38.2 points to 5,467.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and four were untraded.

Medical Developments was the best, up 61 cents or 16.3 percent to \$4.35 with 84,440 shares traded. Benitec climbed 7.7 percent; Ellex, Osprey and Telex were up five percent or more; Pro Medicus improved 4.6 percent; Orthocell was up 3.45 percent; Clinuvel, Cynata, Dimerix and Optiscan rose more than two percent; CSL was up 1.2 percent; with Polynovo up 0.9 percent.

Prana led the falls, down 0.6 cents or 17.65 percent to 2.8 cents with 594,180 shares traded. Paradigm lost 17.25 percent; Reva fell 14.7 percent; Kazia shed 10.5 percent; Airxanders contracted eight percent; Antisense was down 7.4 percent; Patrys was down 6.7 percent; Impedimed fell five percent; Uscom lost four percent; Immutep, Mesoblast and Nanosonics were down more than three percent; Cochlear, LBT, Oncosil and Starpharma shed more than two percent; with Pharmaxis, Proteomics, Resmed and Volpara down more than one percent.

## [DR BOREHAM'S CRUCIBLE: MARIJUANA](#)

By **TIM BOREHAM**

Doobie or die – a day of reckoning is nigh for cannabis corner stocks.

Starring (in order of appearance):

**Cann Group** (ASX code CAN, share price \$1.76, market cap \$188.1 million, shares on issue 106.9 million)

**MMJ Group** (MMJ, 19 cents, \$43.7m, 230.15m shares)

**Zelda Therapeutics** (ZLD, 3.6c, \$27.2m, 755.3m shares)

**Impression Healthcare** (IHL, 1.8c, \$8.4m, 467.2m shares)

**Roto-Gro Int** (RGI, 32c, \$33.0m, 103.2 shares – 18.4m escrow)

**THC Global** (THC, 46.5c, \$59.2m, 127.3m shares – 37.5m escrow)

**Botanix Pharmaceuticals** (BOT, 7c, \$53.0m, 757.4m shares)

**Auscann** (AC8, 48.5c, \$149.9m, 309.1m shares – 132.7m escrow)

**Medlab Clinical** (MDC, 35.5c, \$73.8m, 208.0m shares)

**Elixinol Global** (EXL, \$2.50, \$311.4m, 124.55m shares – 77.9m escrow)

**MGC Pharmaceutical** (MXC, 3.3c, \$39.6m, 1.2b shares)

**BOD Australia** (BDA, 40c, \$27.8m, 69.4m shares)

Globally, the cannabis sector has seen a year of transformation with widespread liberalization of cannabis drug laws, amid creeping cultural acceptance of the herb as both a medicinal and recreational tool.

Despite a pull-back in valuations, the ASX-listed cannabis sector has continued to sprout like some weird new strain of Quebec Gold, Granddaddy Purple or New York City Diesel. With far too many to cover, this is a non-comprehensive potpourri.

Like Tesla chief Elon Musk toking on a doobie at a media conference in dope-friendly California, it's all out in the open: medical cannabis is now legal in 22 countries (with South Korea heading down that path) and in 35 US jurisdictions. In early November medical dope became legal in Britain and South Korea is moving in the same direction.

According to Cann Group CEO Peter Crock, cannabis is only just emerging as an "interesting disruptor" in both the medical and recreational spheres.

“We see it starting to move in a far more rapid way than originally expected,” says Mr Crock, who likens “cannabis years” to dog years in terms of the pace of change.

## **Shifting attitudes**

The shifting attitudes are also being reflected in the utterances of at least some of our home-grown pot stocks, who are talking just as much about the potential of North American recreational markets as therapeutic uses.

With ‘dope for fun’ legalized in California, 10 other US states and now Canada, it’s easy to see how companies are succumbing to the siren call of the recreational sector. The value of the legal recreational market is not known, although in California it’s already meant to be bigger than the wine industry.

The trends have not been lost on alcoholic drinks maker Constellation Brands, which spent \$US4 billion to increase its stake in Canada’s Canopy Growth from 9.9 percent to 38 percent. Separate US market research guesstimates the size of the global prescription cannabis market at \$US12 billion, but expected to grow to \$US100 billion by 2025.

Prepared by the inaptly named Prohibition Partners, the Oceania Cannabis Report predicts the Australian medical cannabis market will be worth \$1.2 billion by 2024 and then \$3 billion by 2028. The firm also expects the number of patients to grow to around 400,000 in the next 10 years.

But for all the hype, the Australian medical marijuana game is heavily regulated and clinical take up is slow. According to the Federal medical regulator, 1,771 applications had been approved for special access arrangements as at the end of October.

But that hasn’t stopped grower wannabees from flooding the Office of Drug Control with close to 200 applications from budding growers and import/exporters.

## **No spare seats in ‘cannabis corner’**

Depending on what stocks you include, the ASX ‘cannabis corner’ now fills up a whole room, with 20 to 30 members. And they’re still coming, with Cronos Australia - an arm of established Canadian supplier Cronos - mulling a listing and \$50 million capital raising that would value the company at up to \$200 million.

(Altria, which makes Marlboro cigarettes, reportedly wants to buy the Canadian parent).

Almost five years since the pioneering listing of Phytotech Medical (now MMJ Group Holdings), the jury remains out on which pot stocks have the most viable and credible business models.

With talk of cannabis-infused beer, honey and gin, opportunism abounds - as well as a degree of silliness. For example, shares in sports mouthguard maker Impression Healthcare surged 124 percent after doing a distribution deal with a US company that makes cannabis chewing gum.

Will future US presidents protest that while they did dope in their college days, they did not swallow?

Others have taken the 'selling shovels to the miners' approach and are selling the paraphernalia instead. For instance, Roto-Gro international boasts a hydroponic set-up that can boost yields by 60 to 85 percent. At the same time THC Global (formerly The Hydroponics Company) has moved away from equipment to a farm-to-pharma strategy.

This includes a presence in the Canadian recreational market and the supply of third-party medicinal products to New Zealand where, unlike here, docs can prescribe cannabis treatments without specific regulatory assent. Way to go, bro!

### **Cann-do attitude**

The biggest medical pot stock by market capitalization, Cann Group became the first company to grow the stuff locally, at an undisclosed site in Melbourne.

Cann is now spending \$100 million building a bespoke facility at Tullamarine Airport, which puts a different slant on the term 'flying high'. So far, the company has harvested 24 crops, which have been purchased by Victoria's Department of Agriculture for clinical trials and is being used in the State's paediatric epilepsy trials.

Cann's September quarterly report showed revenue of \$2,000, so it's off and racing.

But Cann's Tullamarine capacity of 40,000kg to 50,000kg highlights the perils for growers of relying on the domestic medical market. Let's do the sums: 50,000kg is 50 million grams, with the average patient requiring only one gram a day. Put another way, Cann's capacity alone is more than 130 times current requirements.

"We will be able to cater for all Australian regulatory uses multiple times over," Mr Crock says. "That's why exports are so important, as is getting up to scale and being locally competitive."

In Canada, though, the recent legalization of recreational cannabis resulted in a shortage of medical material and "they are screaming for product".

### **Clinical trials matter**

Zelda Therapeutics chief Dr Richard Hopkins says the dynamics between the recreational and medical markets are still unfolding, with the former spurring a boom in wellness products such as cannabis and oils.

With the recreational stuff about two percent of the cost of medical dope, Dr Hopkins says that having a clinical emphasis - in view of a value-added product - is crucial.

Zelda has launched trials for sleep, anxiety and pain - the three broadest indications. Run in conjunction with the University of Western Australia and the California -based Aunt Zelda's, the insomnia trial - the most advanced - is in phase II.

“Clinical trials are really hard, but that’s why we’re doing it,” Dr Hopkins says. “We are not vertically integrated. We are not involved in growing and extracting. We are not a Jack-of-all-trades and master of none.”

Botanix is also in the clinical trial game, with three programs targeting skin conditions. The most advanced is a phase II acne study, due for completion in mid-2019, with a phase Ib psoriasis study underway and a phase II atopic dermatitis trial just been approved.

The second biggest ASX pot stock, Auscann, said in October that it had completed pilot production of a cannabinoid capsule to treat chronic and neuropathic pain. The company says it is on target to supply the market next year.

“These medicines will then be taken through Auscann’s clinical development program for registration of an approved cannabinoid pain management pharmaceutical product,” the company says.

The company says its hard-shell capsules are a superior delivery method to cannabinoids delivered by oral liquids and sprays, or soft-shell gelatine capsules.

Unusually, Medlab Clinical has two cannabis drugs on the market: Nanabis for cancer pain and Nanabidial for chemotherapy-induced nausea and vomiting.

### **Are cosmetics and food additives the winning strategies?**

Locally, dope medications are only available under an Australian Therapeutic Goods Administration special access scheme and the process of educating general practitioners has only just begun.

Cognisant of the medical hurdles, some of the pot stocks are targeting the food additive and cosmetics markets that don’t require such a high standard of clinical proof.

Led by global hemp expert Paul Benhaim, Elixinol owns the established supplements business, Hemp Foods Australia, while it’s also a big supplier of industrial hemp in the US. In the six months to June 30, 2018, Elixinol sold \$12.5 million of cannabis dietary supplements, while here the hemp-derived foods business turned over \$2.3 million.

MGC Pharmaceuticals (as in Medical Grade Cannabis) actually produced a line of cosmetics under the Derma Plus brand, which are available in Britain’s upmarket Harvey Nichols stores.

But MGC is in the process of selling its cosmetics business to Canada’s Cannaglobal, in return for a 10 percent Cannaglobal stake and a five-year supply deal.

That leaves the Europe-focused MGC targetting its seed-to-pharma strategy revolving around growing the stuff at a state-of-the art facility in Malta and its epilepsy treatment Cannepil.

BOD Australia has established skincare lines but is dabbling with cannabis-based ones, as well as a sublingual wafer to deliver medical cannabis.

## **The maple syrup nexus**

Once better known for its mooses and maple syrup - not that we're into national stereotypes - Canada led the way on medical marijuana and has now liberalized recreational dope after some bruising public debate.

Canadian dope stocks also have a huge bearing on our market: Cann is 23 percent owned by Aurora, while Canopy Growth accounts for 11 percent of Auscann.

These days, pot pioneer MMJ is a global cannabis investment company, the biggest of its nine holdings being a 27 percent stake in Canada's Harvest One.

## **Pot stocks take a breather**

Valuation-wise, most of the pot stocks have retracted sharply from their euphoric highs experienced in January and February.

Over the last 12 months stocks including Zelda, Medlab, TPI, MGC, Esense, Stemcell, Lifespot and Creso have halved in value.

It remains to be seen whether this is the correction we had to have, or the onset of the sector going to pot.

Of course, market sentiment overall has been abysmal and 'biotechie speccies' will be among the first to suffer.

## **Dr Boreham's diagnosis:**

There's little doubt that the Canadian and US markets for both medical and recreational dope are capacious - and growing.

But so too is the competition, with no shortage of established providers. As with any other agricultural commodity, the laws of supply and demand will come to the fore.

For what it's worth, your columnist believes that a handful of the cannabis corner inhabitants will do okay.

But many will make a hash of it because they don't have a unique offering in a commoditized market that happens to have more allure than soy beans or grain bushels.

Consolidation of the sector looks inevitable, both here and in Canada where 150 cannabis stocks vie for attention, not to mention the early adopters – Israel and Colorado.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His displayed knowledge of cannabis strains derives strictly from Google and not first-hand experience.***

## INVION

Invion says the Australian Taxation Office has ruled on its demerger and shareholders will vote on the demerger and the issue of 208,520,753 director options.

Invion said that shareholders would vote to issue "long term incentive" options to five directors, exercisable at the 30 percent premium to the share price on the date of issue, within four years of that date and vesting in equal tranches on February 1, 2019 and December 31 2019, 2020, 2021 and 2022.

The company said it proposed to issue chief executive officer Dr Greg Collier 136,288,074 options, Thian Chew 27,257,615 options, Dr James Campbell and Alan Yamashita 20,433,211 options each and Dr Mitchell Glass 4,088,642 options, with the further issue to Dr Collier of \$150,000 in "short term incentive" shares.

The company said that the extraordinary general meeting would vote on the demerger of the respiratory assets into Chronic Airways Therapeutics and an in-specie distribution of shares, as well as the adoption of the employee option plan and the election of director Alan Yamashita.

In a separate announcement Invion said it had received "an appropriate" draft class ruling from the Australian Taxation Office relating to the Chronic Airways Therapeutics demerger and proposed capital return.

Invion said that the ATO confirmed that the tax implications to Invion shareholders who held their shares on capital account were that no part of the in-specie distribution of the Chronic Airways Therapeutics shares would be treated as a dividend for income tax purposes.

The company said that to the extent the amount of the in-specie distribution was less than the cost base of the Invion share, the cost base and reduced cost base of the Invion share were reduced by the amount of the in-specie distribution.

Invion said that shareholders would make a capital gain if the amount of the in-specie distribution in respect of the Invion shares they owned at the time of the in-specie distribution was more than the cost base of the shareholder's Invion share, with the capital gain equal to the excess.

The company said that Australian resident shareholders who were individuals or trusts could apply the capital gain tax 50 percent discount to this capital gain where certain conditions were satisfied and foreign resident shareholders should be able to disregard the capital gain on the basis that their shares were not taxable Australian property.

Invion said that the proposed amount of capital returned to Invion shareholders was unchanged at 0.03159 cents per Invion share.

The company said that a final class ruling would be published by the ATO after the transaction was completed.

The meeting will be held at the Clarendon Hotel, 209-215 Clarendon Street, South Melbourne on January 30, 2019 at 12pm (AEDT).

Invion was unchanged at 1.8 cents with 1.1 million shares traded.

## GENETIC TECHNOLOGIES

Genetic Technologies says it has a joint venture with the Shanghai, China-based Blockshine Technology Corp to develop blockchain in the biomedical sector.

Genetic Technologies said the joint venture company called Blockshine Health would be through its subsidiary Gene Ventures Pty Ltd and it would invest \$250,000 for a 49 percent stake in the joint venture.

Genetic Technologies was up 0.1 cents or 16.7 percent to 0.7 cents with 24.5 million shares traded.

## LBT INNOVATIONS

LBT says joint venture company Clever Culture Systems has filed a US Food and Drug Administration 510(k) application for its APAS Independence instrument.

LBT said the application covered both the automated plate assessment system (APAS) Independence and the associated urine analysis module.

The company said the filing was an “important milestone” supporting the expected launch of the APAS Independence in the US in 2019.

LBT said it had placed the first APAS Independence in the US for investigational use at the Minneapolis, Minnesota-based Hennepin Healthcare System .

The company said that in October 2016, Clever Culture Systems received 510(k) de novo approval for the original manual version of the APAS as a class II medical device and tested 10,000 patients in a series of clinical trials in the US and Australia over 12-months, demonstrating “the core artificial intelligence and imaging capability of APAS, [and] de-risked the regulatory path to market and was a global first”.

LBT said the current submission was predicated on the new device to be comparable or substantially equivalent to the existing device already cleared by the FDA.

The company said it was “not aware of any competing 510(k) submissions against its predicate, once again making this a global first”.

LBT said that from 510(k) submission there was a 90-day review process, with opportunities for the company and the FDA to communicate, and during this time the 90-day process may or may not stop depending on the nature of the review questions.

LBT chief executive officer Brent Barnes said the submission was “a culmination of years of development work on both the physical instrument development as well as the [artificial intelligence] platform”.

“I’d like to acknowledge the hard work of our team and partners in putting together a comprehensive dossier,” Mr Barnes said.

LBT fell 0.2 cents or 2.4 percent to 8.1 cents.

## LBT INNOVATIONS

LBT says it has received \$1,849,059 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

LBT said that the funds related to expenditure for the year to June 30, 2018.

## BIONOMICS

Bionomics says it has received \$654,000 in licencing revenue from the Cancer Therapeutics Co-operative Research Centre (CTX).

Bionomics said CTX had licenced two targets to Pfizer under a potential \$US460 million (\$A647 million) deal.

Bionomics fell half a cent or 4.35 percent to 11 cents.

## ELLEX MEDICAL LASERS

Ellex says it has begun trading on the US over-the-counter quality exchange (OTCQX) under the codes ELXMY and ELXMF.

Ellex said the decision to list on the OTCQX supported its strategy to increase its market share in the US.

Ellex was up 3.5 cents or 5.5 percent to 67.5 cents.



### [THC GLOBAL GROUP \(FORMERLY THE HYDROPONICS COMPANY\)](#)

THC says it has two medicinal marijuana permits from the Office of Drug Control, allowing for cultivation and production at the company's Queensland facility.

THC said the granting of the permits was the next step in its "farm-to-pharma medicinal cannabis strategy".

THC was up 3.5 cents or 8.1 percent to 46.5 cents.

### [CRESO PHARMA](#)

Creso says it has completed the acquisition of Kunna Canada, as well as its Medellin, Colombia-based registered subsidiary Kunna Colombia.

Creso said completion of the acquisition gave it a presence in the Colombian market for its food additives products and a foothold in the growing Latin American region.

The company said it paid for the acquisition by issuing 8,212,121 shares and 1,212,120 performance shares to Kunna vendors.

Creso was up one cent or 2.9 percent to 36 cents.

### [ELIXINOL GLOBAL](#)

Elixinol Global has welcomed US President Donald Trump's signing of the 2018 Farm Bill, removing hemp from the Controlled Substances Act.

Elixinol was up 10 cents or 4.2 percent to \$2.50.

### [NEUROTECH INTERNATIONAL](#)

Neurotech says it has developed a new strategy for US market entry for its Mente Autism training system, focusing on partnerships with certified clinicians.

Neurotech said the change would enable it to enter the US market earlier than planned, with first shipments expected by July 2019.

Neurotech was unchanged at 4.5 cents.

### [TELIX PHARMACEUTICALS](#)

Telix says it has appointed Nannette Rich as the head of US sales and marketing.

Telix said Ms Rich would have commercial responsibility in North America, with an initial focus on the company's Illumet prostate cancer imaging program.

The company said Ms Rich was its first commercial appointment, reflecting its focus on the US market.

Telix said Ms Rich previously worked for Burroughs Wellcome, now Glaxosmithkline, as well as Cytoc Corp, Covidien, Tyco Healthcare-Mallinckrodt and KV Pharmaceuticals.

The company said Ms Rich held a Bachelor of Science from the Columbia-based University of Missouri.

Telix was up 3.5 cents or 5.7 percent to 65 cents.