



Biotech Daily

Friday February 3, 2017

Daily news on ASX-listed biotechnology companies

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- * **BOTANIX EXPANDS PERMETREX LICENCE TO ALL TOPICAL DRUGS**
- * **MEDADVISOR INTEGRATES HEALTHNOTES, OZDOCSONLINE**
- * **SIRTEX INTERIM CEO NIGEL LANGE STARTS ON \$740k**

MARKET REPORT

The Australian stock market fell 0.42 percent on Friday February 3, 2017 with the ASX200 down 23.8 points to 5,621.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and one was untraded.

Benitec was the best, up as much as 178 percent on the Nasdaq and 90.9 percent to 21 cents on the ASX, before closing up nine cents or 81.8 percent at 20 cents with 11.9 million shares traded (see below).

Cellmid climbed 6.7 percent; Mesoblast was up 5.1 percent; Avita, Living Cell, Opthea and Osprey improved more than four percent; Factor Therapeutics and Viralytics were up more than three percent; Atcor, Genetic Signatures, Medical Developments, Sirtex and Starpharma rose more than two percent; Airxpanders, Cochlear, Compumedics and Impedimed were up one percent or more; with Clinuvel, CSL, Ellex and Nanosonics up by less than one percent.

Anteo led the falls, down 0.2 cents or five percent to 3.8 cents with 607,868 shares traded.

Cyclopharm, Oncosil and Orthocell fell more than four percent; Acrux was down 3.1 percent; IDT shed 2.9 percent; Actinogen, Admedus, Pharmaxis and Polynovo were down more than one percent; with Resmed down 0.3 percent.

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

By TIM BOREHAM

Medlab Clinical (MDC) 80c market cap \$78m
MMJ Phytotech (MMJ) 22c market cap \$41m
MGC Pharmaceuticals (MXC) 4c market cap \$28m
Botanix (BOT) 4.6c market cap \$11m
Zelda Therapeutics (ZLD) 3c market cap \$10m
Creso Pharma (CPH) 23c market cap \$8m
Auscann (AC8) not yet listed
Esense-Lab (ESE) not yet listed

Whoopee! Local investors are now spoiled for choice when it comes to exposure to the listed medical marijuana sector, which didn't even exist two years ago.

But how much of the stash on offer should punters inhale? The sector shows great promise, as exemplified by the Turnbull government's decision last year to legalise clinical use under strict conditions.

But like a carefree 1970s Nimbin hippie, the sector still has much growing-up to do and it's hard to get to the nub (or should that be bud?) of the companies' shifting strategies.

The ASX roll call of pure-play pot stocks now amounts to four: pioneer MMJ Phytotech, MGC Pharmaceuticals and the recently listed Zelda Therapeutics and Creso Pharma.

Another, Esense-Lab (ESE) was due to list on Jan 13, but as yet has not penetrated the deep fog of the ASX listing process. Esense's shtick is the phytochemical profiling of targeted plants, including not just cannabis but ginseng, saffron, sandalwood and "other rare medicinal plants and species".

Multi-pronged biologics house Medlab Clinical (MDC) in November received assent from local authorities to import cannabis from Canada, for the use in clinical trials on cancer patients suffering "intractable" cancer pain.

We'll also throw in Cellmid (CDY), which is assessing its midkine (growth factor) portfolio for the treatment of conditions such as chronic kidney disease, heart failure and cancers (as well as balding).

Collaborative pre-clinical (animal) studies carried out in Spain suggest that when combined with medical cannabis, midkine halts the spread of an aggressive brain cancer called glioblastoma.

Auscann (AC8), another pure pot play, is due to list in February by way of a back-door listing with TW Holdings.

The sector is as tight as an expertly-rolled reefer: biotech veteran Dr Stewart Washer heads up Zelda, which has close ties with Auscann. Dr Washer also sits on the Auscann board, which is chaired by his father (and former Federal Member of the House of Representatives) Dr Mal Washer.

Creso chair Boaz Wachtel used to run Phytotech, which merged with MMJ shortly after its pioneer listing in January 2015.

We'll take it as read that cannabis is a globally proven remedy for a variety of ailments including epilepsy, AIDS/HIV, multiple sclerosis, anxiety and depression and, of course, cancer pain relief.

Some treatments revolve around the psychoactive component THC, but most players stress the goodness of the cannabinoids (CBDs) which are not high inducing.

Adding to the clinical credibility, Rich-Lister Barry Lambert and his wife Joy last year donated \$33 million to the Sydney University for further research into the use of cannabis to treat childhood epilepsy.

Last year's Narcotics Drugs Amendment Bill opened the way for medical-grade cannabis to be made available to needy patients, as well as for research. Much of the practical implementation is up to the states, with NSW and Queensland also moving down the legalisation path - but oh so cautiously. Victoria has legalized medical marijuana for certain conditions and the State Government has grown its own and turned it into a standardized medication for children with epilepsy.

Therapeutic Goods Administration consent is also needed and that poses another regulatory overlay.

Given the novelty, it's impossible to define the potential size of the local market. In a marketing "white paper" commissioned by MGC, the University of Sydney last year took a stab and valued the local market at a theoretical \$60 million a year, based on the Canadian experience.

Despite that, Australia remains a relatively small market (familiar story?) with most of the players emphasising a global strategy.

Israel (a renown medical research centre) and Canada (where medical pot has long been legal) feature heavily in the corporate narratives.

For instance, Auscann gets supply from Canopy Growth Corp, the world's biggest grower. The company also has a joint venture with licenced Chilean grower Fundacion Daya.

Probably wisely, the companies are honing specific targets rather touting their potions and devices as a cure-all.

Zelda's repertoire includes eczema and sleep disorders. The company also recently entered research collaboration with Curtin University for a stand-alone treatment for pancreatic cancer.

Creso is focused on animal health and this month claimed first European Union approval for two CBD-based animal feed additives, while Botanix back-doored into Bone Medical for its novel transdermal drug delivery technology Permetrex for prescription products for skin diseases including acne, psoriasis and atopic dermatitis.

In the US, Medical Marijuana Inc subsidiary Kannaway LLC claims to be the first “hemp lifestyle network” to offer CBD botanical products. The Kannaway Gold product is all-natural – isn’t all non-synthetic cannabis? – and “packaged pure with no other ingredients or additives”.

The new premium hemp oil is decarboxylated (shed of carbon dioxide) to maximize CBD content and put through an additional filtration process to remove the hemp oil’s excess waxes, chlorophyll and plant material, giving the oil its golden colour and refined taste.

MGC meanwhile is targeting the skin care market. The company is in clinical studies with human volunteers in Slovenia and is targeting sales in the third quarter of 2017.

On listing, Phytotech claimed to be the “first multinational, vertically integrated medical cannabis company”.

The company’s Swiss subsidiary Satipharm describes its micro gel capsules – to be sold as a dietary supplement -- as the “only medical cannabis produced to have demonstrated safety in a clinical trial program”. The MMJ Phytotech story has become complicated because it has entered into a deal to sell its United Greenery Holdings and Satipharm subsidiaries to listed Canadian company Harvest One, of which MMJ owns 60 percent.

MMJ last week received a pointed ASX query over the alleged tardy timing of the release of an announcement that Harvest One has increased its proposed capital raising to fund the transaction, from \$C15 million to \$C25 million.

MMJ conceded that while it could have been more responsive, any delay was “administrative in nature only”. According to MMJ’s response, “the company has acted to ensure more timely information flow in future”.

To date, the dope companies have taken great care to distance them from the recreational sector, which will always be shrouded by controversy despite public opinion consistently favouring legalization.

But with Canada pondering legalizing non-medical use, MMJ is now targeting “direct supply to the Canadian medicinal AND recreational markets”.

Across the border, the wave of state-based liberalization is in danger of being wound back, with Donald Trump’s attorney general Jeff Sessions opining that “good people don’t smoke marijuana”.

Even if they don’t inhale.

PERFORMANCE:

Pot punters haven’t exactly done their dough, with all of the listed stocks trading above the price at which they initially raised capital (bear in mind that MMJ, MGC and Auscann were back-door listings).

Riding the novelty wave, Phytotech shares almost quadrupled in the days after listing, but are now just above their issue price of 20c a share.

Zelda investors who weighed in at 2.5c are well ahead – the shares trade around 3c – but those who exited at December’s peak of 4.4c were astutely aware that a high never lasts.

Creso shares bounded from their 20c issue price in October last year to a “high” of 36c, but now trade around 23c.

Medlab Clinical has been the star performer, listing at 20c in July 2015 and now trading at 80c.

DR BOREHAM’S VERDICT:

Picking the likely winners and losers out of this pot-pourri of stocks is almost impossible, given the lack of historical market information and the companies’ wildly varying strategies.

Despite the reasonable on-market performance valuations remain low, with the two biggest, Medlab and MMJ, commanding \$80 million and \$40 million market capitalisations, respectively.

We suspect the ones that develop properly clinical validated products and delivery systems will prevail, although we can’t see any of them being troubled by the need for a dividend policy in the next few years.

The companies that merely sell the weed with little value adding will be competing in a highly commoditised market.

MMJ Phytotech has the benefit of its 60 percent exposure to a Canadian grower with two established brands.

The US website Marijuanastocks.com lists close to 100 listed medicinal and recreational listed suppliers, with alluring names such as Totally Hemp Crazy and Mountain High Acquisitions.

Then again, there’s the risk that too much of a clinical focus will result in too much sophistry, with needy patients priced out of the official market and back to the illicit reefers and backyard bong.

By all means take a punt, preferably with a handful of stocks to mitigate the risk.

Just don’t call it sober investing.

**** Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Nor is he a licenced financial adviser.***

[BENITEC BIOPHARMA](#)

Benitec jumped as much as 178 percent on news that it can deliver its BB-201 technology for age-related macular degeneration to the back of the eye.

On the Nasdaq overnight, Benitec climbed \$US2.84 or 177.5 percent to \$US4.44 before closing up \$US2.15 or 134.4 percent at \$US3.75 with 10,034,901 US shares traded.

Today, Benitec chief executive officer Greg West told Biotech Daily: "We have gene therapy vectors that take our drug BB-201 to the back of the retina".

In a media release the company said it had made "significant progress" with its DNA-directed RNA-interference (ddRNAi) technology for ocular diseases, through the collaboration with the San Francisco, California-based 4D Molecular Therapeutics to identify new viral vectors for delivery therapies to the back of the eye using direct intra-vitreous injection.

The company said that chief scientific officer Dr David Suhy would present the results at the Association for Research in Vision and Ophthalmology Asia meeting and the Translational Vision Summit in Brisbane February 5 to 8, 2017.

Dr Suhy said that "a commercially attractive route of administration is a significant step forward in the program".

"One of the major limitations of most ocular gene therapy applications is the use of a highly complex surgical technique called sub-retinal injection for delivery into the eye," Dr Suhy said. "We are developing viral vectors which can efficiently transduce cells within the retina following an office-friendly, intra-vitreous injection."

"Being able to deliver drugs in therapeutically relevant concentrations is a key challenge in drug development," Dr Suhy said.

"It has taken significant time and effort, but we believe that these outcomes demonstrate the commercial applicability of having a vector that can transduce the retina following an intra-vitreous injection," Dr Suhy said.

"The [age-related macular degeneration] program is our first program in this space and we anticipate being able to build a ddRNAi franchise for other ocular indications, in particular retinal diseases, using these novel viral vectors as a key component in that platform," Dr Suhy said.

Benitec said its ddRNAi technology was a combination of gene silencing using RNA interference coupled with the long term therapeutic activity of gene therapy vectors.

The company said that lead ocular candidate BB-201 was designed to treat patients with wet age-related macular degeneration, through the long term expression of the therapeutic short hairpin RNA from a single injection.

Benitec said that BB-201 combined a new adeno-associated virus capsid (AAV) and a recombinant DNA cassette engineered to express steady-state levels of three short hairpin RNA (shRNA) that inhibited vascular endothelial growth factor (VEGF) A and B and placental growth factor (PIGF), three clinically validated targets whose expression was shown to lead to the progression of the disease.

On the ASX today, Benitec climbed as much as 10 cents or 90.9 percent to 21 cents before closing up nine cents or 81.8 percent at 20 cents with 11.9 million shares traded.

[IMPEDIMED](#)

Allan Gray Australia says it has increased its substantial holding in Impedimed from 50,304,651 shares (13.44%) to 56,088,235 shares (14.95%).

Allan Gray said it bought and sold shares between October 11, 2016 and January 31, 2017, with the largest acquisition 600,729 shares for \$473,979 or 78.9 cents a share. Impedimed was up 1.5 cents or 1.9 percent to 82 cents with 1.3 million shares traded.

ACRUX

Allan Gray Australia has further reduced its substantial holding in Acrux, from 12,071,272 shares (7.25%) to 10,288,842 shares (6.18%).

Allan Gray said that on February 1, 2017 it sold 1,782,430 shares for \$570,768 or 32.0 cents a share (BD: Feb 2, 2017).

Acrux fell one cent or 3.1 percent to 31 cents.

PHARMAXIS

Australian Ethical Investment says it has increased its substantial shareholding in Pharmaxis, from 15,956,240 shares (5.03%) to 19,297,634 shares (6.05%)

Australian Ethical said that it bought the shares between March 4, 2016 and February 2, 2017 with the single largest acquisition 456,000 shares for \$131,643 or 28.9 cents a share.

Pharmaxis fell half a cent or 1.8 percent to 26.5 cents.

BIONOMICS

Bionomics says Merck Sharp and Dohme will pay a \$US10 million (\$A13.1 million) milestone for its BNC375 Alzheimer's disease cognitive dysfunction collaboration.

Bionomics said it completed the first milestone in the collaboration with the Kenilworth, New Jersey-based Merck to develop novel candidates for cognitive dysfunction associated with Alzheimer's disease and the milestone was for the first administration of a candidate therapy in a clinical trial (BD: Jun 24, 2014).

In 2014, Bionomics received an upfront payment of \$US20 million (\$A21.2 million) for the Merck & Co cognitive dysfunction collaboration (BD: Aug 19, 2014).

Bionomics said the BNC375 program, targeting Alzheimer's disease and other central nervous system conditions, could be worth up to \$US506 million including milestones, but not including royalties on product sales.

In 2012, following validation in preclinical models of memory deficit Bionomics nominated BNC375 as its drug candidate for Alzheimer's disease and said it was preparing for clinical trials and strategic partnering of BNC375, a positive allosteric modulator of the alpha-7 nicotinic acetylcholine receptor (alpha-7 nAChR), a target for the improvement of memory and learning deficits in illnesses like Alzheimer's disease (BD: Dec 14, 2012).

In October 2012, Bionomics presented two posters showing the alpha-7 compounds outperformed benchmark compounds (BD: Oct 16, 2012).

Bionomics said that Merck would fund all research and development, including clinical development and would be responsible for commercialization of any products.

Today, Bionomics chief executive officer Dr Deborah Rathjen said the milestone "provides validation of the utility of our drug discovery platform to identify high-quality candidates as well as our strategic approach to partner selected assets," Dr Rathjen said.

"The portfolio of products under our collaboration with MSD are designed to address cognitive dysfunction in important [central nervous system] indications and Alzheimer's disease is of chief importance among these as there remains an urgent need for new treatments," Dr Rathjen said.

Bionomics was unchanged at 36.5 cents with 1.6 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has “a substantial expansion” of its licence to the Permetrex skin delivery technology, beyond cannabinoids.

Last year, Botanix executive director Matt Callahan said the Permetrex technology was developed by Dr Gene Cooper, who was formerly with Proctor and Gamble and Elan Corporation in Dublin, Ireland and in Philadelphia, Pennsylvania, and said that the company was based in Philadelphia with trials in Australia (BD: Jun 27, 2016).

Botanix did not specify who the licensor of Permetrex was.

The company said that Permetrex was used as the delivery formulation for its BTX-1503 acne treatment, with the first Permetrex human study completed in December 2016 showing safe delivery and minimal irritancy potential (BD: Dec 7, 2016).

Today, Botanix said the licence was limited to using Permetrex with cannabinoids, including the synthetic cannabidiol that formed the active in BTX-1503.

The company said that the licence had been expanded to allow the use of Permetrex skin delivery technology with any drug actives.

Mr Callahan said that “having access to the technology for a range of other drugs provides new opportunities for the company to expand its pipeline of ... skin disease treatments”.

Botanix said that Permetrex provided a more effective way of delivering drugs into the skin that was non-irritating, did not use chemicals that dried the skin and did not require the use of preservatives that could cause allergic reactions.

“Because the underlying drug active is already approved and marketed, new and improved Permetrex-enabled products can be developed quickly and commercialized without the need to submit the new products ... regulatory agency approval,” Mr Callahan said.

Botanix was unchanged at 4.6 cents.

MEDADVISOR

Medadvisor says the first stage of the Healthnotes technical integration for drug compliance has been completed with a new pharmacy application to be installed.

Medadvisor said that following the \$5.5 million Healthnotes acquisition, the roll-out to existing customers would be completed by February 10, 2017, with the new functionality to be launched in March at the Australian Pharmacy Professional Conference (BD: Oct 31, 2016).

The company said that prior to the Healthnotes acquisition, it used Guildlink’s pharmacy product Guildcare to enable and host its medication adherence management mobile telephone application and the Guildlink agreement would end on February 10, 2017.

Medadvisor said it expected to settle its \$150,000 acquisition of Ozdocsonline on February 17, bringing new technologies and expanding its patient network (BD: Jan 22, 2017).

Medadvisor chief executive officer Robert Read said he was “exceptionally pleased with our operational and financial performance over the past year and the first milestone in our technical integration of our software with Healthnotes signifies our evolution as a business”.

“We can now control the entire technical and transactional process on the platform which will deliver key benefits to Medadvisor and its customers, including our ability to speedily launch additional services and enhancements to the platform,” Mr Read said.

“We will derive cost savings as we will no longer be reliant on an external provider to connect pharmacies,” Mr Read said.

Medadvisor was up 0.1 cents or 2.9 percent to 3.6 cents.

SIRTEX MEDICAL

Sirtex says that interim chief executive officer Nigel Lange starts on a base salary of \$740,000 a year including superannuation.

Sirtex said that Mr Lange would receive the salary on a pro-rata basis for the period he is interim chief executive officer and would be entitled to up to a further \$296,000 as his short term incentive and up to \$555,000 as his long term incentive.

Mr Lange was appointed after the company sacked chief executive officer Gilman Wong following an internal and unpublished inquiry into Mr Wong's sale of shares on October 26, 2016, prior to a profit warning on December 9, 2016 (BD: Jan 22, 2017).

Sirtex was up 37 cents or 2.6 percent to \$14.66 with 543,171 shares traded.