



# Biotech Daily

Friday March 23, 2018

*Daily news on ASX-listed biotechnology companies*

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- \* **PINNACLE SAYS IT IS BELOW 5% IN COCHLEAR**
- \* **REGAL REDUCES TO 6% OF AVITA**
- \* **INVION LOSES DIRECTOR WARREN BROWN**

## MARKET REPORT

The Australian stock market followed the US on Friday March 23, 2018, with the ASX200 down 116.5 points or 1.96 percent to 5,820.7 points.

Eight of the Biotech Daily Top 40 stocks were up, 27 fell and five traded unchanged. All three Big Caps fell.

Benitec was the best, up 1.5 cents or 7.7 percent to 21 cents with 207,614 shares traded.

Acrux, LBT, Osprey and Pharmaxis climbed more than three percent; with Bionomics, Ellex and Volpara up more than two percent.

Actinogen led the falls, down 0.3 cents or six percent to 4.7 cents with 2.2 million shares traded.

Optiscan and Prana fell more than five percent; Airxpanders, Factor Therapeutics, Immutep, Mesoblast and Uscom lost more than four percent; Admedus, Avita, Clinuvel, Compumedics, Dimerix, Genetic Signatures, Impedimed, ITL and Starpharma lost more than three percent; CSL, Nanosonics and Polynovo shed two percent or more; Cochlear, Medical Developments, Opthea, Orthocell, Pro Medicus, Psivida and Resmed were down more than one percent; with Neuren, Sirtex and Viralytics down by less than one percent.

## [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.***

## INNATE IMMUNOTHERAPEUTICS

Innate says it expects to acquire Melbourne's Amplia Therapeutics for its focal adhesion kinase cancer program for 18.5 million shares, worth about \$1.3 million.

Last year, Innate said discontinued its MIS416 program trial for secondary progressive multiple sclerosis after a 93-patient, phase IIb trial showed no meaningful or statistically significant efficacy (BD: Jun 27, 2017).

Innate chief executive officer Simon Wilkinson said that "prior to [Innate's] recently terminated clinical development of MIS416 for multiple sclerosis, we were also positioning our immune modulating drug as a potential anti-cancer co-therapy".

"Refocusing on this existing area of our business is a logical move for the company and we are particularly excited to be pursuing certain cancers where the immune system could play an important role in successful treatment strategies," Mr Wilkinson said.

The company said that under the conditional agreement Amplia shareholders would own 45 percent of the total issued capital of Innate and it expected to have about \$2 million in cash and no debt.

Innate said Amplia had two focal adhesion kinase drug candidates, currently referred to as AMP886 and AMP945.

The company said it would focus on reviewing opportunities for MIS416 and advancing the preclinical development of at least one of Amplia's drug candidates, hoping to be phase I ready within 12 months.

Innate was up 5.8 cents or 187.1 percent to 8.9 cents with 122.8 million shares traded.

## ESENSE-LAB

The ASX has suspended Esense under Listing Rule 17.3 and director Dr Brendan de Kauwe has responded to yesterday's claim of Israeli legal action against him.

Esense has a board spill extraordinary general meeting and a separate annual general meeting scheduled for March 29, 2018 to remove directors Haim Cohen, Eran Gilboa and Ilan Saad; and appoint as directors Dr de Kauwe, if he is not re-elected at the annual general meeting, as well as Andreas Gedeon and Faldi Ismail (BD: Jan 29, 2018).

ASX Listing Rule 17.3 says it can suspend a company's securities if "the entity is unable or unwilling to comply with, or breaks, a listing rule; it is necessary to suspend quotation to prevent a disorderly or uninformed market; ASX's rules require the suspension; [or] it is appropriate for some other reason".

The ASX suspension notice did not provide any detailed reason for the suspension.

Yesterday, Esense said it had begun legal action against Dr de Kauwe in the central district court in Lod, Israel, saying it had requested that the Court instruct Dr de Kauwe to comply with the resolution of the board of directors of January 19, 2018 regarding the change in the company's signature rights regarding its National Australia Bank account, which prevented funding ongoing operations (BD: Mar 22, 2018).

Last night, Dr de Kauwe told Biotech Daily that he had posted a website to respond "to the continuous defamatory statements and unsubstantiated allegations made by certain directors of Esense using the privilege of the ASX platform", which was available at:

<https://esense-lab-shareholder-meeting.squarespace.com>.

"I have made repeated requests for, and not limited to; bank statements and balances for Esense's Israeli bank accounts, management accounts, commercial and employee contracts, documents relating to the performance of Allor vaporizers and details of Esense's payroll," Dr de Kauwe said. "To date, Mr Cohen, Mr Saad and Mr Gilboa have refused or failed to provide them."

Esense last traded at 16.5 cents.

## ANALYTICA

Analytica says it is selecting a new US manufacturer for its Pericoach system after the previous manufacturer withdrew US Food and Drug Administration registration.

Analytica said the previous manufacturer was repositioning itself to established high-volume clients and would not assist in the next stage of Pericoach commercialization.

The company said that its Pericoach intra-vaginal pelvic floor exercise training system for women with stress urinary incontinence was a class II medical device in the US which required a US quality system regulation compliant manufacturing facility to be registered with the FDA.

Analytica said it had suspended supply of Pericoach in the US, until a new FDA-compliant manufacturer was registered and that suspension of US sales was “preferable now than later in the year”.

The company said the decision by the previous manufacturer did not affect its ability to supply outside the US and was not expected to make a significant difference in the company’s financial position, as the US sales were primarily for data collection.

Analytica said it would bring forward plans to expedite the next stage of development, which would focus on reducing the cost of production, and it was reviewing several alternative manufacturers.

Analytica chairman Dr Michael Monsour said the previous manufacturer’s decision would “require a change in our operating priorities for a few months”.

“It also provides a significant opportunity to implement product and production improvements that have been waiting in the wings and enhance the value of any future transaction,” Dr Monsour said.

“Upgrading the designs and processes and reductions in cost of goods will be valuable to a potential deal partner,” Dr Monsour said.

Analytica was unchanged at 0.6 cents with 13.5 million shares traded.

## HYDROPONICS

Hydroponics annual general meeting supported the new board but with up to 22.2 percent voting to remove director Alan Beasley.

Last week, a board spill extraordinary general meeting initiated by Mr Beasley removed directors Ian Mutton, Mary Verschuer, Peter Wallace and Hamish MacDonald and elected Mr Beasley, Louis Cattelan, and Gary Radcliffe, with chief executive officer David Radford resigning ahead of the meeting (BD: Mar 15, 2018).

The EGM voted with 68 percent in favor and 32 percent against the board spill resolutions. Today, Hydroponics said that resolutions on Mr Mutton, Ms Verschuer, Mr Wallace, Mr MacDonald and Mr Radford were withdrawn with Steven Xu, Mr Cattelan, and Mr Radcliffe re-elected with more than 87.1 percent of votes.

The company said that a resolution to remove Mr Beasley was supported by 12,846,129 votes (22.22%), opposed by 44,425,687 votes (76.83%) with 548,015 votes (0.95%) at the proxy discretion.

Hydroponics said that resolutions to remove Mr Cattelan, and Mr Radcliffe were defeated by a slightly higher margin, while the remuneration report was passed with 90.36 percent of votes.

The company’s most recent Appendix 3B said that Hydroponics had 85,906,177 shares on issue, with a further 37,764,450 shares not quoted, meaning that support for Mr Beasley’s removal amounted to 10.4 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.

Hydroponics fell four cents or 6.5 percent to 57.5 cents.

## [NOXOPHARM](#)

Noxopharm says it has raised \$10.8 million in a “heavily oversubscribed” placement to sophisticated and institutional investors of 12,000,000 shares at 90 cents a share. Noxopharm said that the funds would accelerate the development of its lead drug candidate NOX66 for cancer.

The company said that the Melbourne-based Bell Potter Securities was the lead manager and bookrunner to the placement, with Sydney’s APP Securities as co-manager. Noxopharm was up three cents or three percent to \$1.03.

## [COCHLEAR](#)

Pinnacle Investment Management Group says it reduced Cochlear holdings to below the five percent substantial shareholder mark, selling 9,618 shares for \$1,821,347.

Last week, a Pinnacle executive told Biotech Daily that his Brisbane-based company owned 49 percent of Hyperion with the registered holders of the shares including the Bank of New York, BNP Paribas, Citibank, HSBC, JP Morgan Chase Bank, NAB Custodial Services, Northern Trust, RBC Investor Services and State Street (BD: Mar 13, 2018).

Today, Pinnacle said it sold 1,146 shares for \$216,954, or \$189.31 a share, on March 15 and 8,472 shares for \$1,604,393 or \$189.38 a share on March 19, 2018.

On March 13 Pinnacle said it held 2,888,056 shares or 5.02 percent of Cochlear and Biotech Daily calculates that believes Pinnacle retains 2,878,438 shares or 5.0018 percent of Cochlear.

The Pinnacle executive told Biotech Daily that the company had sold more shares and would file a replacement notice, which had not appeared at the time of publication. Cochlear fell \$2.39 or 1.3 percent to \$183.02 with 123,146 shares traded.

## [AVITA MEDICAL](#)

Regal Funds Management says it has reduced its substantial holding in Avita from 72,392,312 shares (6.89%) to 61,869,979 shares (5.88%).

Regal said it sold 10,522,333 shares between December 18, 2017 and March 20, 2018, with single largest sale 1,000,000 shares for \$65,000, or 6.5 cents a share, on February 15, 2018.

Avita fell 0.2 cents or 3.3 percent to 5.8 cents.

## [INVION](#)

Invion says that non-executive director Warren Brown has resigned for personal reasons, effective from March 22, 2018.

Invion said that Mr Brown was appointed on November 4, 2011 and was with the company for the 2012 acquisition of Inverseon Inc and the recent development and commercialization transaction for the Photosoft asset.

Invion fell 0.1 cents or 3.6 percent to 2.7 cents with 21.5 million shares traded.