



# Biotech Daily

Friday September 28, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: ITL UP 10%; PRANA DOWN 12%**
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- \* **BIOTRON UP 105% ON BIT225 HIV COMBO 'SIGNIFICANT BENEFIT'**
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- \* **ONCOSIL AGM TO VOTES ON 3.3m CEO DANIEL KENNY LOAN SHARES**
- \* **CVC TAKES 9.4% OF UNIVERSAL BIOSENSORS**
- \* **'FREEMAN ROAD' REDUCES TO 6% OF RESAPP**
- \* **MMJ POSTPONES PHYTOTECH SALE EGM ONE WEEK**
- \* **ANATARA LOSES DIRECTOR IAIN ROSS**

## MARKET REPORT

The Australian stock market was up 0.43 percent on Friday September 28, 2018 with the ASX200 up 26.4 points to 6,207.6 points.

Eighteen of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and six were untraded.

ITL was the best, up 1.5 cents or 9.7 percent to 17 cents with 10,000 shares traded.

Factor and Genetic Signatures climbed more than seven percent; Optiscan and Telix improved more than six percent; LBT, Mesoblast and Nanosonics were up more than four percent; Benitec, Cynata, Medical Developments, Oncosil and Pro Medicus rose more than two percent; Polynovo and Starpharma were up one percent or more; with Clinuvel, Cochlear, Ellex and Paradigm up by less than one percent.

Prana led the falls, down 0.6 cents or 12.2 percent to 4.3 cents with 11,500 shares traded.

Avita, Imugene and Prescient fell more than four percent; Osprey lost 3.3 percent; Compumedics and Impedimed shed more than two percent; Orthocell was down 1.7 percent; with CSL, Resmed and Volpara down by less than one percent.

[DR BOREHAM'S CRUCIBLE: FOOTY FINALS BIO-SPORTS SPECIAL](#)



**By TIM BOREHAM**

**Acrux:** ACR; share price 22 cents; market cap \$37 million

**Cogstate:** CGS; share price 57 cents; market cap \$68 million

**Dorsavi:** DVL; share price 8.5 cents; market cap \$14 million

**Medibio:** MEB; share price 6.1 cents; market cap \$13 million

**Medical Developments:** MVP; share price \$4.19; market cap \$274 million

**OBJ:** OBJ; share price 2.3 cents; market cap \$42 million

**Paradigm Biopharma:** PAR; share price 90.5 cents; market cap \$114 million

**Regeneus:** RGS; share price 19 cents; market cap \$40 million

**Rhinomed:** RNO; share price 28.5 cents; market cap \$34 million

**Uscom:** UCM; share price 15.5 cents; market cap \$21 million

Drugs and sport do not make for the most comfortable of bed fellows at times: just ask US cyclist Lance Armstrong, world champion shrieker and occasional tennis player Maria Sharapova or the entire Essendon Football Club, whose 'Whatever it Takes' motto took on a sinister meaning in 2013.

But in a more legitimate guise drugs (and medical devices) are an integral part of any professional sport, with the possible exception of darts and synchronized swimming.

Even then we can't be sure.

When it comes to servicing our fast running, high leaping and tough tackling athletes, the Australian biotech sector is there to serve.

And with four Australian Football League and National Rugby League teams vying for the ultimate prize, this weekend, what better time celebrate its role?

In this collectible Grand Final Bio-Sports Special Edition, the Dr Boreham's Crucible examines the life science stocks that help (or should help) prepare the stars for the big day, as well as monitor their on-field performance and pick up the pieces (such as shot knees and dodgy hamstrings) afterwards.

As a Melbournian, your columnist is biased unapologetically to the oval-balled game with 18 players (and in the case of Collingwood, the umpires) on their side.

Go ABC!!\*

\*Anyone but Collingwood

## **Before the game**

**Acrux** is more about generics these days but the company remains synonymous with Axiron, its roll-on testosterone product that commanded the gorilla's share of the US market before being eroded by generic alternatives and a regulatory crackdown.

Still, we wonder how many footballers will reach for their Rexona Sports on Saturday morning with the faint hope that the deodorant supply line has become mixed up with the testosterone supply.

In terms of delivering other (approved) drugs more effectively, **OBJ** could go all the way with a product called Bodyguard, a wearable patch that delivers non-drug pain relief directly to an injury.

Bodyguard results from OBJ's program to develop the world's first transdermal delivery system that improves the performance of products (such as cosmetics) delivered through the skin.

The key to OBJ's know-how is the use of physical science (magnetics) rather than chemistry to achieve this aim.

In clinical programs, Bodyguard is touted as being more effective than orally delivered drugs.

## All eyes on the KPIs

For frustrated footy fans and players alike, the Modern Game is all about measurement, whether it be the Telstra Tracker, the positioning 'heat map' or 'other key performance indicators' (KPIs).

For coaching staff, the ability to measure and analyze how players move their limbs is a useful tool in preventing injuries and ensuring they achieve their KPIs (known in the old days as 'kicking a bag' or 'getting leather poisoning').

Consisting of gyroscopes, accelerometers and magnetometers, **Dorsavi's** wearable wireless devices measure the way people twist and step.

The sports version, Viperform, is deployed by the Australian Football League (AFL, or Footy, as all Aussie kids call it), the National Rugby League (NRL), Cricket Australia and the Australian Institute of Sport, as well as major US competitions.

The most popular module, the Athletic Movement Index, allows sports administrators to benchmark players in terms of susceptibility to injury.

Adding to Dorsavi's local sporting cred, running hero Herb Elliott was chairman until he retired at last month's AGM.

While Aussie rules is sometimes known as 'aerial ping pong' (a term coined by novelist Frank Hardy for the rapid end-to-end ball movement), the maker of non-invasive cardiac and pulmonary devices can claim an even higher, albeit less rapid, calling.

You see, **Uscom's** BP+ device was used to measure the blood pressure of 90 British service men and women scaling the heights of Mount Everest.

It's also been used on the International Space Station, which should make the central BP measurement of heaving athletes a cinch.

Uscom (as in ultrasonic cardiac output monitors) has forged a quiet but successful path in the global medical device sphere since listing in December 2003.

## Wounded in action

You know you've made it in medical science when your company's product is regularly cited by name in broadcasts to millions of viewers.

That's the case with **Cogstate**, which has developed a more reliable concussion test than the traditional 'count my fingers' routine (we dare say that if the player is a valuable match winner, nine or eleven fingers would have been enough for them to take to the field again), or the now rather unreliable 'Do you know who the Prime Minister is?'.

These days, the duty of care to players is much more onerous and the lawyers are doing their best to enforce this: several players are suing their former clubs alleging the cumulative effects of concussion have left them with brain injuries.

The Cogstate test is a screen-based tool that can deliver a result within 15 minutes, with a claimed high reliability rate.

Not that Cogstate can rest on its laurels: a company called **Hitiq** is mulling an ASX listing, based on its concussion-detecting analytics that are embedded in a humble mouth guard.

Commentators are also prone to utter ‘they’ve gone for the green whistle’ when a hapless prone player is hoisted on a stretcher.

The Green Whistle is not a reference to the umpires’ time-honored device to regulate play, but alludes to **Medical Developments’** lead analgesic product, Pentrox.

A reformulation of the methoxyflurane product used by ambulance services here since 1975, Pentrox is now sold in dozens of countries.

With more regulatory approvals pending, it’s a green light for Medical Developments in its quest to replace opioid-based first-line pain relief.

Sadly, for the injured player, the Green Whistle signals a red light and the rest of the match ‘warming the pine’ (bench).

## **The physical aftermath**

Sport: so nourishing for the body and soul and the secret to a long and healthy life.

Er, not quite. When it comes to the rough and tumble footy codes, few players emerge unscathed without knee or joint issues or, in some cases, cognitive impairment.

But knees first: **Paradigm Pharmaceuticals’** anti-inflammatory lead compound pentosan polysulfate sodium (PPS) is yet to be approved, but that hasn’t stopped dozens of AFL players using the drug under a special access scheme to treat dodgy knees and joints.

A reformulation of a deep vein thrombosis drug, PPS is known as safe.

While the jury is out on its efficacy, past stars such as Greg ‘Diesel’ Williams and Andrew Walker swear by its restorative effects.

Dr Boreham’s Crucible covered Paradigm in last week’s column.

If PPS doesn’t work, **Regeneus** is developing stem-cell and immunotherapies for disorders including osteoarthritis and musco-skeletal disorders.

A 20-patient phase I study for Progenza, the company's knee osteoarthritis treatment, identified a "rapid and sustained reduction in knee pain".

Regeneus has some way to go win the AFL's or NRL's seal of approval (and let's face it when you're not a betting company it's that little bit harder).

But Regeneus does have a tie-up with Japanese biopharma manufacturer AGC.

Meanwhile, **Neuren** plays in the cognitive impairment space.

While the company's main targets currently are the neurological disorder Rett syndrome and Fragile X syndrome, in future Neuren could well provide relief for sportspeople who have had the odd knock or three to the noggin during their careers.

We don't use the term 'sportspeople' just to be politically correct, by the way.

From footy to kickboxing, sisters are doing it for themselves and that means in terms of serious injury, they're increasing doing it to themselves.

## **The mental aftermath**

Given the pressures placed on professional sportspeople to stay at the top of their game, mental health issues are rampant.

But at least they're being acknowledged, with AFL star Lance Franklin and US swimmer Michael Phelps exemplars of admired athletes who have acknowledged their struggles with the black dog.

Phelps is on the board of **Medibio**, which has developed an algorithmic application-based tool to screen, diagnose and monitor mental health.

To push its sporting credential further, Medibio's corporate health arm has a deal with the AFL to monitor the mental health of its employees.

The Minneapolis based Medibio recently delivered some depressing news of its own for investors: the abrupt departure of CEO Jack Cosentino.

Whatever the whys and wherefores of his exit, it wasn't an amicable one.

## **Dropped to the reserves**

Like tendonitis-plagued Rafael Nadal during his US Open semi-finals, some biotechs have been forced to retire prematurely from the sporting arena.

The nasal device company **Rhinomed** started the great medical devices race with its Turbine device, a plastic clip like device that attaches to the nose.

Elegant in its simplicity, the idea of Turbine is that by forcing open the nostrils, more air is delivered to the lungs.

While Turbines remain on sale, Rhinomed's emphasis has since turned to a variant called Mute, to tackle the larger sleep apnoea market.

Rhinomed enjoyed the zealous advocacy of British cyclist Chris Froome, who was recently cleared of allegations his performance was enhanced by more than fresh air.

At last report Rhinomed was pursuing a tie-up with Columbia Care, the biggest medical dope operator in the US, to devise nasally delivered medical cannabis products.

Not quite performance enhancing, but no doubt one for the World Anti-Doping Agency's (WADA) list of banned substances.

And speaking of the drugs enforcer, one unfortunate nexus between biotechs and sport is the role of a peptide called AOD9604 in the Essendon (AFL) and Cronulla (NRL) doping scandals.

A failed anti-fat drug, AOD9604 (Anti Obesity Drug, geddit?) was developed by the listed **Metabolic**, whose 536-patient trial in 2007 showed conclusively that it did not work.

Metabolic later morphed into **Calzada** and then renamed itself **Polynovo**, which then off-loaded the Albatross Of Doping to its inventor and chief advocate in a fire sale.

The anti-doping authorities alleged AOD9604 was one of the substances allegedly taken by the allegedly unknowing players, although in the case of Essendon the players were allegedly pinged for taking other alleged substances, as well. Allegedly.

We're not quite sure about the progress or otherwise of AOD9604 in private hands, but at last report the substance remained popular with bodybuilders on the black market.

Good luck to 'em.

Meanwhile, there are 10 aforementioned Australian-listed biotechnology companies with a collective market cap of about \$650 million, eagerly watching every kick, handball, try and pirouette; not to mention every concussion, bone-break and anterior cruciate ligament tear.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His last sporting pursuit - high school ping pong - was remarkably injury free.***

## BIOTRON

Biotron says its 27-patient, phase II, combination trial of BIT225 with anti-retro-viral drugs for HIV-infected patients shows “statistically significant immunological benefits”.

Biotron chief executive officer Dr Michelle Miller told Biotech Daily the difference between the active and control groups in the BIT225-009 trial was “statistically significant”.

“The headline results indicate that BIT225 has had a profound effect on a source of virus that persists in the presence of antiretroviral drugs,” Dr Miller said.

In its media release to the ASX Biotron said the results of the BIT225-009 trial “indicate that BIT225 is having a unique effect in patients, over and above viral suppression seen with current antiretroviral drugs [and the] data is consistent with targeting and eradication of virus from macrophage reservoir cells”.

The company said the Bangkok and Chang Mai, Thailand-based, double-blind, placebo-controlled trial was designed to assess the safety and anti-viral activity of 12 weeks of dosing of once-daily 200mg doses of BIT225 in combination with anti-retro-viral drugs in treatment-naïve HIV-positive subjects.

Biotron said that at the end of the 12 weeks of combination dosing, all patients continued to take anti-retro-viral drugs as per standard protocols.

The company said that a separate, smaller cohort of nine subjects took once daily doses of 100mg BIT225 or placebo for detailed pharmacokinetic profiling of BIT225 and its interactions with anti-retro-viral drugs.

Biotron said that preliminary analysis showed that BIT225 was well-tolerated at the 200mg once daily dose, with no severe adverse events or withdrawals.

The company said that the human immuno-deficiency virus “hides in long-lived cells known as macrophages” and the cellular source of virus persisted even in people taking anti-retro-viral drugs that resulted in no detectable virus in their blood.

Biotron said the persistence of the virus caused serious problems including an immune system which aged more quickly and other problems such as HIV-associated neuro-cognitive disorder, or AIDS-related dementia.

The company said the BIT225-009 trial data showed that the body’s immune system recognized the dead virus, which triggered a range of changes to the immune cells that fought disease and in addition to the beneficial immunological effects, there was a significant reduction in the level of the macrophage activation marker sCD163 in the BIT225-treated population by the end of the treatment period.

Biotron said that higher levels of sCD163 were linked with worse clinical outcomes in patients and the reduction of sCD163 might provide additional clinical benefit.

The company said that eradication of the virus, produced by long-lived reservoir cells, was “central to an eventual HIV cure strategy”.

“We knew from laboratory-based studies that BIT225 targets and kills virus that hides in long-lived reservoir cells,” Dr Miller said.

“The challenge was how to show this in humans,” Dr Miller said.

“No one has done this before, and there were no guidelines to follow,” Dr Miller said.

“We have had to use a range of techniques to show that BIT225 has done what we expected it to do, that is, clear out virus from these reservoirs,” Dr Miller said.

“This has included the development and use of new cutting-edge assays, which has been a time-consuming process,” Dr Miller said.

“We know that antiretroviral drugs do not clear cellular reservoirs [and] HIV-infected people have to take drugs for their lifetime to keep virus under control,” Dr Miller said.

“This trial shows for the first time that there may be a way to clear one of the main cellular reservoirs,” Dr Miller said.

Biotron was up 2.1 cents or 105.0 percent to 4.1 cents with 90.1 million shares traded.



## ELIXINOL GLOBAL

Elixinol says it has raised \$40 million in a placement to institutional and sophisticated investors at \$1.85 a share a 14.0 percent discount to the last closing price of \$2.15. Elixinol chief executive officer Paul Benhaim said the funds would be used to increase the capacity of its US marijuana-derived cannabidiol production facility to prepare for increasing levels of demand, increase its sales force and marketing efforts in the US and Europe, provide additional working capital and build an Australian medical marijuana facility, pending a licence from the Office of Drug Control. The company said that Bell Potter Securities was the lead manager to the placement. Elixinol fell 23 cents or 10.7 percent to \$1.92 with 875,344 shares traded.

## BIONOMICS

Bionomics has requested a trading halt “pending an announcement regarding the results of its BNC210 phase II clinical trial in patients with post-traumatic stress disorder”. In 2016, Bionomics said it had began the 160-patient, phase II trial of BNC210 in adults with post-traumatic stress disorder (PTSD) with a primary objective to determine whether BNC210 caused a decrease in symptoms of PTSD as measured by the US National Centre for PTSD Clinician-Administered PTSD Scale (BD: Jun 30, 2016). The company said at that time that secondary objectives included the determination of the effects of BNC210 on anxiety, depression, quality of life, and safety. Trading will resume on October 2, 2018 or on an earlier announcement. Bionomics last traded at 50 cents.

## ONCOSIL

Oncosil will vote to issue chief executive officer Daniel Kenny 3,300,000 “performance dependent loan shares”. Oncosil said that the shares would be issued at the 30-day volume-weighted average price to the date of issue and the loan would be interest-free unless it was not repaid within three years of the loan, or within one month of resignation or cessation of employment, at which time it would accrue interest at nine percent per annum. The company said that 50 percent of the shares would vest on total shareholder return achieving 15 percent compound annual growth rate, with the second tranche vesting on total shareholder return achieving a 25 percent compound annual growth rate. Oncosil said that the meeting would also vote on the remuneration report and the re-election of director Dr Roger Aston. The meeting will be held at the K & L Gates, Level 31, 1 O’Connell Street, Sydney on October 30, 2018 at 11am (AEDT). Oncosil was up half a cent or 2.6 percent to 20 cents.

## UNIVERSAL BIOSENSORS

CVC says it has increased its substantial shareholding in Universal Biosensors from 13,956,430 shares (7.89%) to 16,651,964 shares (9.42%). CVC said that between September 4 and 27, 2018 it bought 2,695,534 shares for \$673,314 or an average price of 25.0 cents a share. In August, the Sydney-based CVC said it bought the 2,004,466 shares at 25.65 cents a share (BD: Aug 31, 2018). Universal Biosensors was unchanged at 24 cents.

### [RESAPP HEALTH](#)

Freeman Road Pty Ltd, for The Avenue account, says it has reduced its substantial holding in Resapp from 44,000,000 shares (7.59%) to 43,500,000 shares (6.28%). The substantial shareholder notice, signed by director Tee Yen Ng of St George's Terrace, Perth, Western Australia, said Freeman Road bought 2,200,000 shares for \$148,696 or 6.75 cents a share on August 11, 2017 and between April 23 and September 13, 2018 sold 2,700,000 shares for \$439,546 or 16.3 cents a share and was diluted in last week's placement which raised \$7.5 million at 22 cents a share (BD: Sep 19, 2018). Previously Biotech Daily has reported that the Australian White Pages has a Freeman Road located in Maroubra, Sydney, while the LinkedIn page for Trevor Marchant said that he was the owner of Freeman Road Pty Ltd (BD: Jul 24, 2015).

Biotech Daily attempted to contact Mr Marchant and Freeman Road at that time, but without success.

Resapp was up one cent or five percent to 21 cents with 3.3 million shares traded.

### [MMJ PHYTOTECH](#)

MMJ says the extraordinary general meeting to vote on the sale of Phytotech Therapeutics to Harvest One Cannabis for \$C8 million has been postponed.

MMJ said the meeting to vote on the sale was due to take place today but the sale was conditional on it and Harvest One obtaining shareholder and regulatory approvals and the Toronto Stock Exchange Venture Exchange was yet to provide approval.

The company said it expected approval next week and the meeting had been postponed to October 5, 2018 at 2pm (AEST) at the same venue, the Westin Hotel, 1 Martin Place, Sydney

MMJ fell one cent or 3.3 percent to 29 cents with 1.7 million shares traded.

### [ANATARA LIFESCIENCES](#)

Anatara says that non-executive director Iain Ross has resigned "for personal reasons" effective from September 30, 2018.

Anatara chair Sue MacLeman said that Mr Ross had "made a significant contribution to Anatara's board since his appointment as a non-executive director in 2013, soon after the company's inception and prior to the ASX listing".

"His experience and insights will be greatly missed," Ms MacLeman said.

The company said it intended to recruit a non-executive director with experience in human health.

Anatara was up four cents or 8.9 percent to 49 cents.