



Biotech Daily

Friday October 15, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.69 percent on Friday October 15, 2021, with the ASX200 up 50.3 points to 7,362.0 points. Twenty-one of the Biotech Daily Top 40 stocks were up, nine fell and 10 traded unchanged. All three Big Caps were up.

Next Science was the best, up 10.5 cents or 8.6 percent to \$1.33, with 129,620 shares traded. Cyclopharm climbed 5.95 percent; LBT and Nanosonics improved more than four percent; Alterity, Antisense, Cynata, Dimerix, Polynovo, Telix and Universal Biosensors were up more than three percent; Genetic Signatures, Imugene, Kazia, Oncosil and Paradigm rose more than two percent; Clinuvel and Mesoblast were up more than one percent; with Cochlear, CSL, Opthea, Pro Medicus, Resmed and Volpara up by less than one percent.

Actinogen led the falls, down one cent or 9.1 percent to 10 cents, with 5.6 million shares traded. Prescient fell four percent; Proteomics shed 2.35 percent; Immutep and Starpharma were down more than one percent; with Avita, Medical Developments, Neuren and Orthocell down by less than one percent.

[DR BOREHAM'S CRUCIBLE: A TRIP THROUGH PSYCHEDELIC DRUGS](#)

By **TIM BOREHAM**

Emyria Ltd (EMD): share price 22 cents, market cap \$56 million, 12-month share gain 162 percent

Creso Pharma (CPH): share price 11 cents, market cap \$132 million, 12-month share gain 266 percent

Incannex Healthcare (IHL): share price 35.5 cents, market cap \$429 million, 12-month share gain 283 percent

Little Green Pharma (LGP): share price 66.5 cents, market cap \$155 million, 12-month share price gain 108 percent.

Turn on, tune in and don't drop out. The push to develop psychedelic drugs is gaining momentum, but not quite in the way the 1960s counter-culture figure Dr Timothy Leary intended.

The late Harvard psychologist strongly advocated the use of mind-bending drugs - notably lysergic acid diethylamide (LSD) - to expand creativity and engender a general sense of well-being.

Now, the advocates are all about using psychedelics - notably 3,4-methylene-dioxy-methamphetamine (MDMA) and psilocybin to treat difficult conditions such as post-traumatic stress disorder (PTSD), treatment-resistant depression (TRD), general anxiety, dementia, anorexia and alcohol and nicotine addiction.

Many readers will be aware - and we're not passing judgment - that MDMA is the party drug ecstasy, better known as molly. Psilocybin is the active component of magic mushrooms, which have long been known to put the fun into fungi.

Other mind-bending substances of interest are LSD and the horse tranquillizer ketamine (also known as the party drug Special K).

As with cannabis, these drugs have a long history of medical experimentation. LSD was first isolated by Swiss chemist Dr Albert Hofmann in 1943, after which he experienced a vivid trip on his bicycle (in more ways than one) after accidentally ingesting the drug.

MDMA was first synthesized by German pharma house Merck in 1912. Meanwhile, psilocybin has long been ingested by central and south American indigenous peoples, who discovered their evening mushroom stew had a bit more zing than usual.

In the 1960s psychedelic drugs became synonymous with swingers' "key parties" and Vietnam war protests. Serious research came to a halt after US President and moral guardian Richard Milhous Nixon (Tricky Dicky – seeing as how we're using a lot of colloquial expressions) declared a war on drugs – a battle that has lasted much longer than the Indochina one.

As with medical (and recreational) pot, attitudes are changing - albeit slowly.

According to advocacy group Mind Medicine Australia, more than 120 psychedelic trials have been carried out in the last decade.

Mind-blowing valuations

Overseas, psychedelic drug developers are commanding, er, mind-blowing valuations. Take the \$US3.2 billion market worth of the German based, Nasdaq listed Atai Life Sciences which is targeting conditions including traumatic brain injury and schizophrenia.

The private, Oxford-based Beckley Psytech raised \$US80 million in August and Chicago-based venture capital group Palo Santo in July gathered \$US35 million to invest in a portfolio of psychedelic stocks.

Locally, four ASX cannabis stocks have turned (expanded?) their minds to the sector: Emyria, Creso Pharma, Incannex Healthcare and Little Green Pharma.

Backed by tech entrepreneur Daniel Petrie and venture capital fund Possible Ventures, the private Sydney-based Psylo has raised \$1.1 million for early research. Earlier, the Melbourne based Psychae Institute pocketed a handy \$40 million from a very mysterious, unnamed American biotechnology company.

Navigating the regulatory maze

For drug development to happen in earnest, the rules need to change.

Last year, the local Therapeutic Goods Administration rejected entreaties to reschedule MDMA and psilocybin from schedule nine to schedule eight (as it did for medicinal cannabis in 2016).

Schedule nine means it's a prohibited drug which can be used in approved clinical trials; schedule eight means it's a controlled substance that opens the way to registration and reimbursement.

Mind Medicine Australia argued the decision was based on flawed science, including the contention that these substances were addictive.

In April this year the agency agreed to a re-think and commissioned an independent expert review (as you do).

In late September, the three-person expert committee of academics released the results of its review, which was based on a whittled-down sample of nine clinical studies on the two drugs.

To cut a long story short, the advocates seized on the committee's headline conclusion that both drugs appeared to have "statistically significant" results, but the evidence was strongest for MDMA.

The well-tolerated substances “showed promise in highly selected populations, but only where these medicines are administered in closely supervised settings and with intensive professional support”.

Of course, the advocates weren't suggesting otherwise. But they did gloss over the committee's criticisms of the “variable” quality of many of the trials which, for example, included ‘blinded’ participants who appeared well-aware of what they were taking.

The Advisory Committee of Medicines Scheduling meets on November 3, with the TGA expected to announce its decision in the first week of December.

And elsewhere?

Of course, Australia is – duh – just Australia.

In the US, psychedelics were declared a banned substance in 1970, with “no currently accepted medical use”.

Official attitudes have thawed since then, to put it mildly, with the US Food and Drug Administration awarding “breakthrough” status to MDMA and psilocybin, to treat PTSD and treatment-resistant depression (TDR).

In July, the US Congress passed a law compelling the National Institute of Health to fund research into psychedelic and cannabis therapies, with an emphasis on MDMA for PTSD.

In May this year, the agency granted approval to the Multidisciplinary Association of Psychedelic Studies (MAPS) to study the use of MDMA by healthy volunteer therapists.

MAPS has completed 10 FDA-approved MDMA studies so far and is overseeing another seven.

Health Canada has a similar exemption for therapists, which points to the notion of a “guided experience” rather than users being left to pop the pills at home.

Emyria (EMD)

Emyria's work initially centred on synthetic cannabis as an alternative to the botanical stuff, which varies in quality.

The company started out its ASX life as Emerald Clinics in early 2020. The company still operates these specialist cannabis clinics, from which it gleans a useful bank of client information for its patient database.

Interestingly Emyria notes a “chronic oversupply” of cannabis, with licenced Canadian growers destroying 279,000 kilograms of the stuff in 2020.

That goes against a narrative about medical cannabis being in short supply.

But we digress and so does Emyria, which is developing a “scalable, evidence-based” clinical model for MDMA, in exclusive partnership with Mind Medicine Australia.

The crux of Emyria’s focus is a proposed phase II trial to treat PTSD with MDMA, but it appears some way from being launched.

Emyria also boasts exclusive access to a file of more than 100 MDMA analogues: a library of compounds developed by the University of Western Australia over the last decade.

Emyria is currently browsing through the library for the most useful ones, with screening to date showing “excellent purity and long-term stability.”

Emyria is executive-chaired by Dr Stewart Washer, who is also on the boards of the listed Orthocell, Cynata and Botanix. Dr Washer and his family interests account for about 19 percent of Emerald’s register.

Creso Pharma (CPH)

Pot-stock Creso’s ASX journey since listing in 2016 has been unpredictable, to put it politely, and the wild ride continues into the psychedelic sector.

Creso had planned to merge with the Ontario based Red Light Holland, which is not a knock shop but a purveyor of “magic truffles” (psilocybin) to the legal recreational market in the Netherlands.

The new entity would have listed on the Canadian exchange under the code TRIP - and we rue we’ll never see that apt ticker.

In 2019, Creso was to have been taken over by Canadian pot play Pharma Cielo but that one didn’t get past the altar either. However, the acquisition of the smaller Canadian grower Mernova Medicinal was duly completed in 2018.

In March this year, Creso acquired Canadian outfit Halucenex, a clinical stage company focused on using psilocybin to treat PTSD, TRD and anxiety.

Halucenex is one of only three Canadian companies licenced to handle psilocybin - 10 kilograms of the stuff at any one time. The psilocybin is synthetic: the company doesn’t forage in the fields for one of the 100-plus varieties of mushies containing the active ingredient.

Creso plans a phase II trial focused on using psilocybin for treatment-resistant PTSD. And in lieu of the Red Light Holland merger, the company is putting on its big boy’s pants for a Nasdaq listing.

Creso co-founder Dr Miri Halperin Wernli is also the president of the \$US1.2 billion Mind Medicine Inc, which gives a clue about Creso’s likely hallucinogenic path.

In the meantime, the company almost doubled (cannabis derived) revenue in the first (June) half, to \$3.06 million, with just over half derived from Mernova.

Incannex Healthcare (IHL)

This one was formerly known as Impression Healthcare, which developed sports mouthguards under the Gameday brand. Despite the advocacy of sports stars, it was never a scalable business and the company executed a graceful double pivot into medical cannabis and then psychedelic therapies.

On the cannabis front, Incannex is tackling conditions including traumatic brain injury, rheumatoid arthritis, irritable bowel syndrome and inflammatory lung conditions. Its most advanced program is a phase II, proof-of-concept trial targeting obstructive sleep apnoea.

On the psychedelic side, Incannex has zeroed in on the use of psilocybin for generalized anxiety disorder. The company notes that seven million Americans and one million Australians suffer moderate to severe anxiety, which makes us more neurotic than them on a per-capita basis.

Pending ethics approval, Incannex expects to launch a phase IIa trial at Monash University's Brainpark facility. It's also yarning with the FDA about an investigational new drug application.

The company cites supportive studies undertaken by New York University, the University of California Los Angeles, Johns Hopkins University and London's Imperial College.

Overall, these studies enrolled just 85 patients, with early results showing the psychedelics could be two to four times more effective as a front-line treatment relative to cognitive behavioral therapy and antidepressants.

Incannex intends to enlist 72 patients in active and placebo arms, undergoing two doses over 10 weeks. They will also undergo weekly psychotherapy sessions.

Incannex chalked up \$1.9 million of revenue from cannabis oil sales in the year to June 2021 and lost \$8.1 million.

As with Creso, Incannex proposes a Nasdaq listing. In mid-September its shareholders voted overwhelmingly in favor of issuing 180 million shares to facilitate an initial public offer for the listing.

Management is girded by Nasdaq listees such as Compass Pathways, which is pursuing phase II psilocybin trials for treatment-resistant depression and is valued at \$US1.25 billion. Incannex already commands a circa \$400 million valuation.

Little Green Pharma (LGP)

In September, Western Australia's health mandarins granted the medicinal cannabis supplier a licence to supply psilocybin to other eligible parties to carry out research.

The company, which is backed by iron ore magnate Gina Rinehart, also said it was "well advanced in planning to sponsor a ground-breaking, Perth-based clinical trial into psilocybin assisted psychotherapy".

The research pertains to conditions including depression, post-traumatic stress disorder and anxiety.

The company reminds uninitiated folk that 'magic mushroom' derived psilocybin induces a psychedelic state through its action on the brain's 5-hydroxy-tryptamine-2A serotonin receptors.

The company has also appointed Dr Stephen Bright as an adviser. A "prominent and highly respected voice in psychedelic medicine", Dr Bright was a co-founder of psychedelic research house Prism and a lecturer in addiction at Edith Cowan University.

"We have developed so much experience over the years through the cannabis industry and we genuinely believe we can now bring that to bear on the development of the psychedelics," Little Green boss Fleta Solomon said.

In the meantime, Little Green will remain focused on supplying the European market with cannabis flowers and oils from its newly-acquired Danish facility.

Dr Boreham's diagnosis:

The simple way of viewing the psychedelic therapies sector is being on the same evolutionary route of medical cannabis, but perhaps a decade behind.

Psylo co-founder Josh Ismin reportedly expects a psychedelic treatment on the market within 10 years. Given the FDA has approved only two cannabis-based drugs, this appears overly optimistic.

As with pot therapies - but even more so - the regulators appear to be largely unconvinced at this stage.

The narrative is likely to be muddied by demand from the recreational market for blue meanies, gold tops and amanitas*. And the psychedelic push is likely to confound regulatory authorities as they mull the marijuana approvals.

Still, money talks loudest and there's no doubting the flood of investment into the sector. If the trend continues, we suspect it will be only a matter of time before the first pure-play ASX psychedelic stock emerges.

Creso cites Credence Research suggesting the market for psilocybin alone could be worth up to \$US25 billion by 2025.

If such bullish sentiment endures, investors should have the trip of a lifetime.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort.

****Your columnist had to look up these terms and hopefully so do you***

MTP CONNECT

MTP Connect says its third report investigates skill gaps in the life sciences workforce highlighted by the Covid-19 pandemic.

The Federal Government-funded MTP Connect said the reports were developed as part of the \$32 million four-year Researcher Exchange and Development within Industry (REDI) program.

The organization said the third report highlighted skills gaps in specific areas that have become more pronounced due to the pandemic, as an addition to the first two reports, which identified a range of gaps to be addressed in the next 12-18 months.

MTP Connect managing-director Dr Dan Grant, said the report explored skills gaps in biosecurity, infectious disease resilience and advanced manufacturing that could inhibit the growth of an industry-ready sector workforce.

Dr Grant said the report discussed the “critical skills needed for vaccine manufacturing, including mRNA vaccines, regenerative medicine, infectious disease resilience and medical countermeasures”.

“We have a shortage of good manufacturing practice (GMP)-trained staff to meet the expected increase in future demand for the manufacture of advanced medical products, such as mRNA manufacturing,” Dr Grant said.

“Our sector also lacks commercial-scale process design expertise, the skills so important to designing efficient medical product manufacturing processes,” Dr Grant said.

Dr Grant said early-stage companies lacked awareness of the different skills “required at various stages along the development pathway which, if not addressed, can stall development of new medical products”.

“We also have a shortage of people with the skills to drive computer-aided drug discovery. It’s these computational, or in-silico, skills that are so critical to early identification of promising drug candidates,” Dr Grant said.

“Taking notice of these gaps and addressing them now will help power the future prosperity of our sector and contribute significantly to higher jobs and economic growth for Australia,” Dr Grant said.

MTP Connect said the reports were a foundation for a contestable program supporting training initiatives targeting identified gaps.

The organization said registration for round three of the REDI contestable program opened today and qualified organizations had until November 30m 2021 to submit programs to address the five key skills gaps identified in the reports.

The report is at: <https://www.mtpconnect.org.au/reports/redi-skills-gap>.

NUHEARA

Nuheara says it has begun its 50-patient, regulatory-directed, hearing aid clinical trial with Sydney’s National Acoustics Laboratory.

Last month, Nuheara said it had approval for the trial of its range of hearing aid products (BD: Sep 15, 2021).

Today, the company said its self-fit hearing aids were designed for over the counter, retail and online sales.

Nuheara said it expected to make a 510(k) submission to the US Food and Drug Administration under the self-fit category by April 2022.

Nuheara said the planned submission was part of its plan to secure broad FDA self-fit hearing aid clearance to meet the expected demand for a new category of over-the-counter hearing aids.

Nuheara fell 0.1 cents or four percent to 2.4 cents with 4.7 million shares traded.

DIMERIX

Dimerix says it will expand the 600-patient Clarity 2.0 phase III trial of DMX-200 for Covid-19 to Australia.

In September, Dimerix said that India's Central Drug Control Organization recommended approval of its 660-patient, phase III trial of DMX-200 for Covid-19 with multiple clinical sites being initiated and ready to begin recruitment (BD: Sep 24, 2021).

Today, the company said that with the University of Sydney's National Health and Medical Research Council Clinical Trials Centre, an initial six sites would begin recruitment in New South Wales, Victoria and Queensland pending approvals.

Dimerix said the Clarity 2.0 protocol was an investigator-led, prospective, randomized, double blind, placebo-controlled study and the primary endpoint would be an eight-point clinical health score measured on treatment day-14, with participants treated for up to 28 days, with longer term outcomes assessed at 26 weeks.

Dimerix was up one cent or 3.6 percent to 28.5 cents with three million shares traded.

MGC PHARMACEUTICALS

MGC has told an ASX query that director Evan Hayes did not trade shares in a closed period and his Appendix 3Y director's interest statement had a wrong date.

The ASX said that MGC announced a \$US25 million (\$A33 million) supply agreement with the Miami Florida based AMC Holdings on August 27 and the first order received on September 29, 2021, with both announcements marked as market sensitive.

The ASX said that Mr Hayes filed his Appendix 3Y saying he bought 295,000 shares between September 28 and 30, 2021 and asked whether Mr Hayes complied with the trading policy and whether he had approval to trade shares which "appears to have taken place while [MGC] was in possession of price-sensitive information?"

MGC said that Mr Hayes sought permission on September 15 and was granted permission to trade shares outside any blackout period and that he was "not in possession of price sensitive information".

"The Appendix 3Y lodged for Mr Hayes on 4 October 2021, incorrectly stated the date of change ... as 28-30 September 2021, when in fact the total acquisition of MGC shares by Mr Hayes occurred after the aforementioned announcement was released to the market at 10:54am on 30 September 2021," the company said.

MGC company secretary David Lim told the ASX: "The actually timing ... was confirmed through my review of trade confirmations that Mr Hayes received from his broker."

MGC fell 0.1 cents or 1.8 percent to 5.4 cents with 7.9 million shares traded.

BOD AUSTRALIA

Bod Australia says it will change its ASX ticket code from BDA to BOD on Monday October 18, 2021.

Biotech Daily notes that Botanix Pharmaceuticals has the ASX ticker code BOT.

Bod fell half a cent or 1.8 percent to 27 cents.

LIVING CELL TECHNOLOGIES

Living Cell has requested a trading halt pending an announcement about "an equity raising to be undertaken by way of an institutional placement and a pro rata offer".

Trading will resume on October 19, 2021, or on an earlier announcement.

Living Cell last traded at 1.1 cents.

MICRO-X

Micro-X says its annual general meeting shareholders will vote to increase its pool of non-executive directors' fees by 133.3 percent from \$300,000 to \$700,000 a year.

Micro-X said the increase in the directors' fee pool was to attract "appropriately qualified non-executive directors and to act quickly if the circumstances require it".

The company said shareholders would vote to issue performance rights to the value of 30 percent the director's base fees, amount to \$30,000 in performance rights to chair David Knox's and \$19,500 in performance rights each to Patrick O'Brien, James McDowell, Yasmin King and Dr Alexander Gosling.

Micro-X the meeting would vote to issue shares in lieu of cash payments for director's fees to Mr Knox, Mr O'Brien, Mr McDowell, Ms King and Dr Gosling.

The company said shareholders would vote on the remuneration report, the re-election of directors Dr Gosling and Mr McDowell, the ratification of the issue of the placement shares and the approval of the 10 percent placement capacity.

Micro-X fell one cent or 3.1 percent to 31 cents.

VISIONEERING TECHNOLOGIES

Visioneering says customer receipts for the three months to September 30, 2021 rose 4.18 percent to a record \$US1,968,000 (\$A2,652,095) compared to the previous year.

Last year, Visioneering posted receipts from customers for the three months to September 30, 2020 of \$US1,889,000.

Visioneering chief executive officer Stephen Snowdy told Biotech Daily that it was a record quarter for revenue for the company's Naturalvue multifocal contact lenses.

The company said it had cash and equivalents of \$US13,161,000 on September 30, 2021.

Visioneering fell 2.5 cents or 2.6 percent to 94 cents.

CRONOS AUSTRALIA

Cronos says it has record sales of its marijuana products in the three months to September 30, 2021, of more than \$1.1 million.

Cronos said the revenue growth from sale of marijuana products in Australian was up 90 percent from the previous three months.

Cronos was up half a cent or 3.1 percent to 16.5 cents.

MEDADVISOR

Perennial Value Management says it has reduced its substantial share-holding in Medadvisor from 56,297,258 shares (14.92%) to 51,492,053 shares (13.64%).

Sydney's Perennial said it bought and sold shares between August 23 and October 13, 2021 with the single largest sale 2,449,254 shares for \$782,037 or 31.92 cents a share.

Medadvisor fell two cents or 6.25 percent to 30 cents.

HYDRIX

Perennial Value Management says it has reduced its substantial share-holding in Hydrix from 10,804,263 shares (6.64%) to 8,463,321 shares (5.16%).

Sydney's Perennial said it sold shares between May 26 and October 13, 2021 with the single largest sale 1,327,416 shares for \$178,807 or 13.5 cents a share

Hydrix fell half a cent or 3.7 percent to 13 cents.

IDT AUSTRALIA

IDT says director Mary Sontrop will retire at the company's annual general meeting on November 16, 2021.

IDT said it appointed Ms Sontrop as a director in 2017 (BD: Mar 1, 2017).

IDT fell 4.5 cents or 6.8 percent to 61.5 cents with 2.2 million shares traded.