



# Biotech Daily

Friday October 21, 2022

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 0.8 percent on Friday October 21, 2022, with the ASX200 down 53.9 points to 6,676.8 points. Twelve of the Biotech Daily Top 40 were up, 17 fell, 10 traded unchanged and one was untraded.

Telix was the best, up 76 cents or 12.7 percent to \$6.76, with 2.4 million shares traded. Impedimed improved 10 percent; Dimerix and Opthea climbed more than three percent; Next Science, Oncosil and Orthocell rose two percent or more; with Alcidion, Avita, Cyclopharm, Pro Medicus, Resmed and Universal Biosensors up by more than one percent.

Actinogen led the falls, down one cent or eight percent to 11.5 cents, with 2.25 million shares traded. Proteomics lost 6.8 percent; Kazia, Patrys and Resonance fell five percent or more; Paradigm and Uscom were down three percent or more; Emvision and Mesoblast shed more than two percent; Atomo, Clinuvel, CSL, Cynata, Immutep and Nanosonics were down one percent or more; with Cochlear, Medical Developments, Neuren and Polynovo down by less than one percent.

## [DR BOREHAM'S CRUCIBLE: WOKE PHARMACEUTICALS](#)

**By TIM BOREHAM**

**Chief executive officer and co-founder:** Nick Woolf

**Board:** Mr Woolf, Matt Hayne (co-founder)

**Financials (June half 2022):** revenue nil, cash \$2.68 million

**Major shareholders:** Mr Woolf 17.5%, Mr Hayne 17.5%, Frazis Capital Partners

### **Woke is a private company**

Amid a worldwide surge of interest in using psychedelic substances to treat stubborn mental health conditions, the ASX, possibly soon, could host its first pure-play drug developer in this (mind) expanding field.

The private Woke Pharmaceuticals plans a \$10 million to \$15 million initial public offer (IPO) and a listing “on a suitable public exchange” in early 2023 – if the market gods behave of course.

Woke is into psilocybin (magic mushrooms) and lysergic acid diethylamide (LSD), so to speak.

To Woke co-founder Nick Woolf, the listing plans reflect the strong investor interest in the Sydney-based company, which strives to develop novel therapeutic therapies as registered medical treatments for mental health disorders and other neurological diseases.

The company has partnered with a number of august institutions, including Monash University Medicines Manufacturing Innovation Centre (MMIC) and Macquarie and Swinburne Universities, in Sydney and Melbourne, respectively; and has also signed up the ASX-listed contract drug maker IDT Australia to make the finished products.

Woke is eyeing the unmet need of the 20 percent of Australians who struggle with mental illness, a statistic that’s probably been boosted by the pandemic lockdown.

“The idea behind psychedelic therapy is that the receptive state the drug confers opens the door to fresh ideas about how to think about the past and future,” says Prof David Nutt, psycho-pharmacologist at the Imperial College London and an adviser to Woke.

### **It’s time, Mr Woolf**

The former head of ASX-listed medical pot stock Auscann, Mr Woolf co-founded Woke with investment banker Matt Hayne in June 2021.

“We literally started with a blank piece of paper but were able to move quickly because of the relationships I had built up in medical cannabis, as well as Matt’s ability to access capital,” Mr Woolf says.

The holder of chemistry degrees from University of Oxford, Mr Woolf was also PYC Therapeutics chief financial officer, and Suda’s (now Arovella) business development manager - and before that - had European equities analyst and investment banking roles.

Mr Hayne has a corporate finance and investment background at institutions including Wilson HTM, Phillip Capital and the Commonwealth Bank. He is a whiz at IPOs, reverse mergers and capital raisings - all of which might come in handy.

Mr Woolf says he was impressed with research, notably from Baltimore’s Johns Hopkins University, showing the benefits of psilocybin (magic mushrooms) for severe depression.

“There’s an undeniable unmet need,” he says. “There are so many opportunities to potentially use psychedelics to change patients’ thinking about what triggers their conditions.”

In practical terms, Mr Woolf tapped the supply chain and research alliances he forged at Auscann, notably with the MMIC in terms of formulating the rapid-acting compound.

## **Have a nice trip**

While there are hundreds of psychedelic compounds, the research and commercial emphasis is on psilocybin and 3,4 methylene-dioxy-meth-amphetamine (better known as MDMA or ecstasy and by youngsters as the party drug, molly).

Broadly speaking, psychedelics work by creating new pathways between neurons in the brain, thus creating psychological, auditory and visual changes. Well before the written word, psychedelic plants were used as therapies and in religious ceremonies. In the 1960s, thousands of clinical papers and several dozen books were written, but the war on drugs meant work was stymied for three decades.

As Morgan Stanley notes in a recent report, in the last 15 years several academic institutions have conducted small studies exploring the potential of psychedelics to address a number of medical indications, including treatment-resistant depression and post-traumatic stress disorder (PTSD).

“The impressive results of these small studies have generated great interest in further exploring the potential of psychedelic therapy,” Morgan Stanley says. (But the Australian regulator takes a different view - see below.)

The current forms of anti-depressant treatment are mostly selective serotonin reuptake inhibitors, or SSRIs, better known by brand names such as Prozac.

“Unlike SSRIs, which dull or mask the symptoms ... psychedelic assisted therapy can change a patient’s fundamental outlook over the course of one to a handful of sessions,” the report says.

## **The regulatory landscape**

In December last year, the Therapeutic Goods Administration (TGA) opted to maintain the schedule nine classification for psilocybin, which in essence means it remains illegal. The TGA cited limited benefit shown thus far and “a high danger for both acute and long-term effects if abused or misused ... due to diversion for illicit purposes”.

Woke says it wasn't all bad news, because the TGA acknowledged the potential worth of the therapy in “highly selected populations” where patients were “clinically supervised with professional support”. Maintaining the regulatory status quo does not affect the ability to use the drug in trials.

“The TGA is seeking further clinical evidence that supports the therapeutic value of psilocybin and outweighs the risks of potential misuse,” Mr Woolf says.

“We agree with this premise and are at the forefront of generating robust data from planned phase II trials of psilocybin, conducted in Australia for the treatment of depression,” he says. “The results of these trials could inform a future application for the down-scheduling of psilocybin.”

Mr Woolf adds the US Food and Drug Administration has designated both MDMA and psilocybin as breakthrough therapies, which makes researching the drugs and the regulatory path to approval easier. To qualify, preliminary clinical evidence must indicate that the drug is safe and has the potential to demonstrate substantial improvement over available therapies.

## **Make room for the 'shroom**

Woke has plans for potentially four trials with psilocybin which, by the way, is synthetically devised (the team doesn't forage for the fungus in the fields with wicker baskets).

The first effort pertains to WP-001, a low-dose or “micro dose” (3.0 milligram or 5.0 milligram) rapid release capsules to treat moderate depression.

The company is seeking ethics approval for a 266-patient phase IIb study, which should kick off before the year is out. The primary endpoint is measured by the Grid Hamilton Depression Score, with secondary endpoints of biomarkers, physiological and neurophysiological measures.

Carried out by Macquarie University and overseen by micro-dosing guru Dr Vince Polito, the randomized, double blinded placebo-controlled trial will be in three parts: safety and dose ranging, drug versus placebo and an open label extension enabling the placebo cohort to be treated. Patients will be treated twice weekly for six weeks.

Patients will also be tested for their ability to simulate driving after such micro-dosing, but will be shouted an Uber home, anyway.

Mr Woolf describes the trial as “ground breaking”: it's the largest well-controlled randomized trial of a psychedelic micro-dose with results expected in 2024.

## **Upping the ante**

WP-002 is a high dose (25 milligram) version tablet, to be trialed for treatment-resistant depression. Overseen by Prof Nutt and the principal investigator at Swinburne University Prof Susan Rossell, the Australian trial will enrol 160 participants with 40 on placebo.

The endpoint is the Montgomery-Asberg Depression Rating Scale, but a key aspect is that the drug administration is accompanied with intense psychotherapy. Bear in mind the patients are likely to have serious issues, such as suicide ideation.

This month, Woke signed a term sheet with Sydney University for a trial using WP-002 to treat alcohol abuse. The phase II randomized trial will enroll 60 patients and we dare say there will be no shortage of takers given the extent of the problem.

The company is also mulling the feasibility of a prolonged grief study, in conjunction with the Brisbane-based Queensland Institute of Medical Research (Berghofer).

## **Lucy in the Sky with Diamonds**

Woke's WP-003 is an early-stage program to discover a novel lysergic acid diethylamide (LSD) analogue pitched at treating anxiety, substance abuse and PTSD.

Synonymous with the 1960s counter culture and supposedly even the inspiration for a trippy-sounding Beatles song\*, LSD was first synthesized by Sandoz's Dr Albert Hoffman in 1938, but he didn't understand its properties until accidentally sampling it 1943. It has been used recreationally since then, but was banned in the US in 1968 and currently is a US DEA schedule I drug, signifying "no currently accepted medical use and a high [no pun intended] potential for abuse".

Hundreds of studies have pointed to the drug being non addictive and an effective treatment for the aforementioned maladies. It is also said to reduce pain and depression for cancer patients and attention deficit hyperactivity disorder. Said to be much more potent than psilocybin, LSD is also more chemically complex and expensive to make.

"With the University of Western Australia, we are trying to simplify the structure of the molecule and modify its side effects," Mr Woolf says. "We are sourcing precursors of LSD from reputable providers and then modifying the chemical scaffold [and] by mid-2023, we hope to have a library of analogues for testing with in-vitro assays."

## **Finances and performance**

In its brief history, Woke has raised circa \$5.5 million to date from investors including Frazis Capital Partners, family offices and wealthy individuals. In a seed round in October last year, the company gathered \$1.55 million at five cents a share (it only intended to raise \$1.25 million).

The company is wrapping up a series A round, initially aimed at raising up to \$3 million, but upsized to \$4 million at 10 cents per share (\$3.6 million is in the bag).

“We have good interest to support an IPO in March to May next year, to raise \$10-15 million at a price of 20 cents or upwards per share,” Mr Woolf says. “But if we can’t IPO, we will do a series B round.”

Meanwhile, a handful of ASX cannabis stocks also dabbling in psychedelics. Emryia (EMD) has a pre-clinical program pertaining to MDMA-like analogues, while Incannex Healthcare (IHL) and Creso Pharma (CPH) propose psilocybin trials to treat generalized anxiety disorder and PTSD respectively.

### **A nice sideline**

Woke also has a partnership with the Canada-based Havn Life to distribute a line of mushroom-derived natural health products under the Woke Health brand, a wholly owned Woke subsidiary, with the rights covering to Australia, NZ, ASEAN and China. (The ASEAN countries consist of Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam.)

The (psilocybin-free) products include Mind Mushroom for “immunity and energy balance”, Lion’s Mane for “brain and body balance” and Reishi Recharge for “Zen support”. Mr Woolf says the company is launching a Shopify electronic-commerce site and is also partnering with bricks-and-mortar retailers.

“I think it’s going to fly off the shelves, to be honest,” he says. “It’s not core to what we are doing, but ... it’s about getting an early return for investors.”

### **Dr Boreham’s diagnosis:**

Mr Woolf says Woke’s work is being carried out with an emphasis on health economics: the degree to which psychedelics can reduce the burden on the healthy system and make people more employable.

In a similar commercial vein, Woke opted for psilocybin over MDMA because there is more research into the latter.

“We felt the data from psilocybin for depression was so compelling it would be a really good entry point for us with novel formulations,” Mr Woolf says.

The Woke journey remains a long slog, but there’s no doubting the level of investor interest given some of the mind blowing - or should that be expanding? - valuations offshore.

So, the message is to turn on, tune in and certainly not drop out.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. \*John Lennon always denied that Lucy in the Sky with Diamonds was a reference to LSD, but there’s no denying the Fab Four were ardent pioneers of psychedelic ‘research’.***

[CRESO PHARMA, EVERBLU CAPITAL  
AUSTRALIAN SECURITIES AND INVESTMENTS COMMISSION  
AUSTRALIAN FEDERAL POLICE](#)

Biotech Daily is aware of media reports on Creso Pharma and its former founder and chair Adam Blumenthal.

Last year, the Australian Securities and Investments Commission (ASIC) told Biotech Daily that it had raided the offices of Everblu Capital, an investor in Creso and Roots Sustainable and other companies, including the delisted Esense (BD: Nov 16, 2021). The chair of Everblu, Adam Blumenthal was at that time the chair of Creso and Roots. A spokesperson for ASIC told Biotech Daily that the Australian Federal Police exercised warrants on behalf of the Commission in relation to “certain market activities, among other things”.

At the time of publication no one had been charged and there was no further information available.

Later that month, Creso said ASIC had required documents, chair Adam Blumenthal had stood aside and James Ellingford was interim chair (BD: Nov 25, 2021).

In an announcement titled ‘Update on Price and Volume Query Response’ Creso said that on November 22, 2021 it “was served with a notice issued by ASIC under Section 33 of the ASIC Act, requiring it to produce certain documents to ASIC in connection with an ASIC investigation”.

The company said that the notice “identified for the first time that ASIC’s investigation includes suspected contraventions by the company, its officers, agents, employees and representatives in relation to trading in its securities”.

“The notice confirmed that it should not be construed as an indication by ASIC that a contravention of the law has occurred, nor should it be considered a reflection upon any person or entity,” Creso said.

Last week, Creso said that Ben Quirin and Jodi Scott would be appointed directors replacing founder Adam Blumenthal, who resigned effective from October 10, and the company intended to change its name to Melodial Global Health (BD: Oct 10, 2022). Creso was up 0.1 cents or 3.1 percent to 3.3 cents with 1.7 million shares traded.

[FEDERAL GOVERNMENT, MTP CONNECT](#)

The Federal Government says it will provide \$13.9 million in biomedical investment through two MTP Connect programs, funding 14 projects.

The Federal Minister for Health and Aged Care Mark Butler said \$7.2 million would be allocated to five medical device projects, including LBT Innovations plate reader and Oncores’ cancer surgery diagnostic imaging system, through the Clinical Translation and Commercialisation Medtech program.

MTP Connect chief executive officer Stuart Dignam said the five projects in New South Wales, South Australia, Victoria and Western Australia “have the potential to address unmet needs and improve the health and well-being of all Australians”.

The Federally-funded MTP Connect said Mr Butler announced \$6.7 million in funding for nine projects as part of the Targeted Translation Research Accelerator program, including research at Deakin University, the Garvan Institute, Monash University, University of Sydney, and the University of Western Sydney.

Mr Dignam said the Targeted Translation Research Accelerator program would fund projects addressing atherosclerosis, cerebrovascular disease, cardiomyopathy and heart failure, as well as mental health and glucose control for those living with diabetes.

## EBR SYSTEMS

EBR says it has identified a battery depletion issue with its Wise endocardial pacing system, but that the issue has not affected patient health or safety, to date.

EBR said that it had identified an insulation breach in the system's transmitter in up-to 6.3 percent of Wise devices to date, that device batteries depleted more quickly than predicted.

The company said that in instances where the battery depletion issue occurred, the Wise system had continued to function as intended, remaining fully operational until battery depletion.

EBR said it did not expect the development to "materially impact the timing or data of headline results" for its pivotal Solve trial, which it said remained on track for release by July, 2023.

The company said that in other trials, enrolment would be subject to the battery issue being resolved first.

EBR said it did not expect the issue to have a material impact on its funding requirements, citing its strong cash position, which it said was sufficient to support a pathway to approval by the US Food and Drug Administration and ensuing commercialization.

EBR chief executive officer John McCutcheon said "we anticipate this matter to be resolved and expect any updates to be included within our [pre-market approval] submission to the FDA [by July] 2023".

EBR fell four cents or 7.2 percent to 51.5 cents.

## ANATARA LIFESCIENCES

Anatara says it has "firm commitments" to raise \$865,000 in a placement at 3.5 cents a share, and will offer a one-for-three non-renounceable rights offer to raise \$832,000.

Anatara said that participants in the placement and entitlement offer would receive one attaching option for two new shares, exercisable at seven cents by December 11, 2025.

The company said that the capital raising was at a 23.9 percent discount to the 4.6 cents closing price on October 18, 2022.

Anatara said that the record date for the rights offer was October 26, it would open on October 31 and close on November 21, 2022.

The company said that the funds would be used to "reach interim read-out in the form of a futility analysis on stage 1 of the irritable bowel syndrome trial".

Anatara said that Adelaide's Taylor Collison acted as lead manager, with the Melbourne-based Candour Advisory Pty Ltd as its advisor.

Anatara fell 0.1 cents or 2.2 percent to 4.5 cents.

## STARPHARMA

Starpharma says it has appointed Hong Kong's Hengan Pharmicare Company to sell and distribute its Viraleze anti-Covid nasal spray in Hong Kong and Macau.

Starpharma said that under the two-year agreement, Hengan would be responsible for sales, final packing, distribution and marketing in Hong Kong and Macau and would be subject to launch performance obligations.

The company said it expected Viraleze to be launched in Hong Kong and Macau in the next two to three months.

Starpharma said Viraleze contained SPL7013, a broad spectrum anti-viral, which was the active ingredient in Vivagel BV for bacterial vaginosis and its Vivagel condom coatings.

Starpharma was unchanged at 60 cents.

### RHYTHM BIOSCIENCES

Rhythm says it has received \$2,705,943 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Rhythm said the rebate related to research and development expenditure for the year to June 30, 2022.

Rhythm was up four cents or 3.5 percent to \$1.19.

### BOTANIX PHARMACEUTICALS

Botanix says its annual general meeting will vote to issue 13,000,000 performance rights to directors and 5,000,000 incentive options to director Dr Stewart Washer.

Botanix said shareholders would vote to issue 6,000,000 performance rights to executive chair Vincent Ippolito, 3,500,000 rights to executive director Matthew Callahan, 1,500,000 rights to chief scientific officer and director Dr William Bosch and 1,000,000 rights each to directors Dr Washer and Danny Sharp, for nil consideration, expiring in four years.

The company said the meeting would vote to issue Dr Washer 5,000,000 options exercisable at 10.2 cents each, by March 22, 2025.

Botanix said shareholders would vote to approve an increase of termination benefits, update the employee incentive plan, increase the maximum issue to 150,000,000 shares.

The company said the meeting would vote to re-elect Mr Sharp and Dr Washer as directors, adopt the remuneration report, approve the 10 percent placement facility, and ratify several resolutions in relation to a prior placement and directors' participation.

The meeting will be held at D2, 661 Newcastle Street, Perth on November 23, 2022 at 9am (AWST)

Botanix fell 0.1 cents or 1.5 percent to 6.4 cents.

### INVEX THERAPEUTICS

Invex says shareholders at its annual general meeting will vote on the issue of 3,600,000 options to four of its directors.

Invex said investors would vote to issue chair Jason Loveridge 1,280,000 options, Prof Alexandra Sinclair 1,120,000 options, Dr Thomas Duthy with 1,000,000 options, and Dr Megan Baldwin 200,000 options, all exercisable at a 50 percent premium to the 30-day volume-weighted average price to its annual general meeting, by December 1, 2026.

The company said investors would vote on the remuneration report, to elect directors Prof Sinclair and David McAuliffe and approve the 10 percent placement capacity.

The meeting will be held at Level 9, Mia Yellagonga Tower 2, 5 Spring Street, Perth on November 22, 2022 at 9am (AWST) and virtually at:

[https://us02web.zoom.us/webinar/register/WN\\_50lsqIBzT-qC8dord8p5vw](https://us02web.zoom.us/webinar/register/WN_50lsqIBzT-qC8dord8p5vw).

Invex was untraded at 59 cents,

### ARGENICA THERAPEUTICS

Argenica says its annual general meeting will vote to issue 2,000,000 options to managing-director Dr Liz Dallimore, exercisable at 65 cents by June 3, 2025.

Argenica said that shareholders would to re-elect chair Geoff Pocock as a director, ratify two share placements and an options issue and approve the 10 percent placement facility.

The meeting will be held at Steve's, 30 The Avenue Nedlands, Western Australia on November 24, 2022 at 3.30pm (AWST).

Argenica was up 2.5 cents or 5.3 percent to 50 cents.

## ACRUX

Acrux says annual general meeting will vote on the issue of \$66,200 of rights to chair Ross Dobinson, and a total of \$38,500 rights each to three directors.

Acrux said the proposed grant of rights to chair Ross Dobinson was 50 percent of his total director's remuneration of \$132,400.

The company said the grant of \$38,500 rights each to Don Brumley, Dr Geoff Brooke and Dr Timothy Oldham was part of their total remuneration of \$85,085 each.

Acrux said the rights would be exercisable within seven years of the date of grant.

Acrux said that shareholders would vote on the reelection of Dr Brooke as a director, the remuneration report and the approval of a 10 percent placement facility.

The meeting will be held at Pitcher Partners, Level 13, 664 Collins St, Docklands, Melbourne, on November 23, 2022 at 10am (AEDT) and online at

<https://meetings.linkgroup.com/ACR22>.

Acrux was up 0.6 cents or 8.2 percent to 7.9 cents.

## RESONANCE HEALTH

Resonance says shareholders will vote on the issue of 1,830,000 performance rights to managing-director Mitchell Wells.

Resonance said the performance rights were in addition to Mr Wells' total remuneration package of \$260,000, and would vest in three equal tranches annually from October 1, 2023, "subject to Mr Wells remaining employed or engaged by the company at the relevant vesting date".

The company said that shareholders would vote to adopt the remuneration report, re-election of Dr Travis Con Baroni as a director, approve the 10 percent placement facility and re-insert proportional takeover bid provisions.

The meeting will be held at 141 Burswood Road, Burswood, Western Australia, on November 24, 2022, at 10am (AWST).

Resonance fell 0.3 cents or 5.6 percent to 5.1 cents.

## STARPHARMA

M&G Investment Funds says it has reduced its substantial shareholding in Starpharma from 27,552,109 shares (6.78%) to 23,619,915 shares (5.78%).

The London-based M&G said that between January 22, 2021 and October 19, 2022, it sold shares in Starpharma with the largest sale 1,068,705 shares for \$1,533,592, or \$1.44 a share on January 22, 2021 and the most recent sale of 450,000 shares for \$286,200 or 63.6 cents a share on October 19, 2022.

## VOLPARA HEALTH TECHNOLOGIES

Volpara says Fred Struve has been appointed a joint company secretary effective immediately, and will continue his current role as general counsel.

Volpara said he would join chief financial officer Craig Hadfield as joint company secretary.

Volpara was unchanged at 60 cents.

## BOTANIX PHARMACEUTICALS

Botanix says it has promoted chief commercial officer Dr Howie McKibbon to chief operating officer, who will prepare for a US review of its sofipironium bromide.

Botanix said Dr McKibbon would focus on preparing for the US Food and Drug Administration review point for its sofipironium bromide new drug application for patients with excessive sweating, expected by April, 2023 (BD: Sep 26, 2022).