

Biotech Daily



Thursday December 21, 2023

Daily news on ASX-listed biotechnology companies

2023 - The Year In Review

The last 12 months were probably the hardest the Australian biotechnology industry has faced since we began reporting in November 2005.

Bionomics, Incannex and Kazia have gone to “the better valuations of the Nasdaq”, while Analytica, IQ3, Oncology One, Osprey, Oventus, Tali, Total Brain, Woke Pharmaceuticals and Zucero have just gone.

Living Cell has become the marijuana-based Algorae, Dr Sean Hall is attempting to salvage what’s left of Medlab Clinical, Dr Sean Parsons is attempting to salvage what’s left of Ellume and the not-all-that-poor-at-all, Johnson & Johnson has ceased its previously keen interest in Australia, joining Pfizer in running the Deputy Sheriff from somewhere called ‘not Australia’.

Hexima. Well, that was a surprise. Who would have thought that a treatment for toe nail fungus wouldn’t be a blockbuster?

Both Auscann and Regeneus have been hoping to conduct a transaction that will reinvigorate their respective fortunes; and while Cardiex still has a pulse, it’s weak. There are others with very little cash who have told the ASX that they are fine and although they don’t have two quarters cash at the moment, there is a capital raising, or a Federal Research and Development Tax Incentive, or increased revenue, belt-tightening, or staff cuts or all of the above, just around the corner. We give them all the benefit of the doubt.

If you think this applies to you, you are not alone. We still love you.

Artificial intelligence

Artificial intelligence –previously known as computer software – was the buzzword of the year with all sorts of companies claiming to be ‘A.I.-this’ or ‘A.I.-that’. Great. They’ve learnt how to program their computers. The most ubiquitous use appeared to be very dubious claims backed up by unreal insights into other people’s material. We were very surprised not to see any A.I.-marijuana-stem-cell-mRNA companies – but Aglorae with the ticker code of 1AI for its marijuana products came close.

Sunshine through the dark clouds

But it hasn't been all bad news – far from it.

In March, Neuren finally won US Food and Drug Administration approval for its trofinetide for Rett syndrome. Okay, partner Arcadia won US Food and Drug Administration approval for Daybue for Rett syndrome. Whatever. It means that apart from payments already made, Neuren earns multi-million-dollar milestones, royalties and one third of the sale of the Priority Review Voucher. In July, Neuren said that Acadia would pay up-to \$US527 million (\$A765 million) to take trofinetide global.

Also in March, the Walter and Eliza Hall Institute's loss of director Prof Doug Hilton proved to be the Commonwealth Scientific and Industrial Research Organisation's gain, with Cambridge University's Prof Ken Smith to take the WEHI reins in May 2024. CSL's former chief operating officer Dr Paul McKenzie replaced managing-director Paul Perrault.

Impedimed doubled in value on news that the US National Comprehensive Cancer Network included its bio-impedance spectroscopy for the first time. And the first quarter of the year ended with the Federal Government pushing its \$15 billion Reconstruction Fund through Parliament, with "medical science" one of seven priority areas.

In April, Immvirx Pty Ltd scratched a few heads by dosing the first patient in an oncolytic virus cancer trial. Who is Immvirx you ask? It's none other than the old Viralytics team of Dr Malcolm McColl and Prof Darren Shafren. They're back! Telix posted first quarter Illucix revenue of more than \$100 million on the same day that Control Bionics announced the 'world's first autonomous driving wheelchair'.

In May, EBR said its 183-patient Wise cardiac pacing device pivotal trial met its primary endpoints with significant improvement against pre-set benchmarks and began the process of its FDA application, hoping to file by April 2024 with approval expected when, and if, the FDA says so.

Melbourne private company Incisive Technologies said the FDA had cleared its Bluecheck for detecting and monitoring tooth decay, and we discovered where former Sienna Diagnostics chief executive officer Dr Kerry Hegarty had been hiding.

Companies raised large amounts of cash including Anteris (twice), Immutep, Imugene, Mesoblast (twice), Opthea and Saluda; Pro Medicus signed more mega-deals; Neuren was awarded more Acadia milestone payments; and it remained never a better time to be a mouse with cancer.

Initial public offers (new companies to the ASX) returned in August with Curvebeam and Cleo. Far too many companies kept us informed of every second patient enrolled in a phase I or II trial, leaving us wondering whether we were being "informed" or "snowed". Companies issued results for 12 patients, then 14 patients, then 23 patients. How about announce the start and end of the trial and then the results? Keep it simple.

Race shifted focus, then lost its CEO, then its board, then re-shifted focus. Impedimed lost its board, then its CEO, but not its focus, which was selling Sozo for body fluid assessment.

In another innovative move (meaning we wished we had thought of it) Paul Hopper and Jennifer Chow at Chimeric introduced Paul Hopper and Leslie Chong at Imugene to Precision Biosciences, earning a \$4.4 million spotter's fee. Perhaps it should be known as a Hopper's Fee? And Prime Minister Anthony Albanese opened CSL's new headquarters in what was once known as Haymarket, is generally called South Parkville, but is technically the City of Melbourne or the suburb of North Melbourne. A Magic Pudding by any other name tastes just as sweet.

More companies than ever closed August with serious revenues for the year, but a few still haven't taken the hint that claiming the Federal Government Research and Development Tax Incentive as revenue is misleading to investors and analysts.

Proving how long a way it was to the top, in September, Prof Andrew Wilks told Biotech Daily that after just 20 short years of development, the US Food and Drug Administration had approved Glaxosmithkline's Ojjaara for myelofibrosis. Ojjaara was previously known as Cytopia's CYT387, discovered by Prof Wilks and his team at Melbourne's Ludwig Institute for Cancer Research. Cytopia was founded in 1999 and listed on the ASX in 2004, and sold to YM Biosciences for \$11 million before ending up at Glaxosmithkline.

Little Green Pharma said a 2,327-patient, three-month study showed that low dose tetrahydro-cannabinol (THC) and high dose cannabidiol (CBD) marijuana "improves quality of life" for moderate to severe anxiety and depression, but didn't improve sleep disorders. Astounding! Ausbiotech chief executive officer Lorraine Chiroiu announced her retirement and Michael Spooner left Mesoblast after 19 years as a director. Pharmaxis said it would become Syntara with a ticker code of SNT and one wit wrote asking if that was pronounced "snot" - which it's not - but has been concreted into our synapses.

In October, Cyclopharm's managing-director James McBrayer announced US Food and Drug Administration approval of Technegas for pulmonary embolism imaging. Mr McBrayer said the company's founders contacted the FDA to discuss approval 32 years ago, in 1991, and after joining the company in 2008 his first contact with the US regulator was the following year in 2009. (Cue AC/DC bagpipe solo ...)

And just three days later, Dimerix announced an "up-to" \$230 million deal for its DMX-200 for focal segment glomerulo-sclerosis (FSGS), later showing great perspicacity in appointing the far-too-long-suffering Antisense managing-director Mark Diamond as its chair. The ducks are lining up as Dimerix continues its trials (and tribulations) under the steady hand of chief executive officer Dr Nina Webster. David Williams, who had relinquished his chair at Medical Developments, took over at Inoviq.

Lots of companies announced annual general meetings to reward the directors with buckets of options and performance rights - despite failing to pay dividends to investors - and some were rewarded with remuneration report strikes or even losing directors and resolutions, especially special resolutions requiring 75 percent majorities. But that's okay because they won't connect the dots, anyway.

Medibio changed its name to Trivarx and had a 20-to-one consolidation so that we wouldn't remember that it used to be Leo 'The Gun' Khouri's Bioprospect and its technology was based on the concept that a cardiac rhythm could predict major depressive disorder - which some say is rather unlikely.

Dr Megan Baldwin stepped back from many years as Opthea’s chief executive officer, Ausbiotech held its annual Octoberfest and we were into November and the end of the year. “Hallelujah” chorused the worlds of biotech and finance.

Epsilon founder and deputy chair Alan Beasley kicked off some fairly interesting board spill machinations, which won’t be resolved until next year, with the other two directors signing ASX announcements as “the majority of the board” which is as true as claiming “a 66.6 percent success rate” in a trial where only one of three mice died.

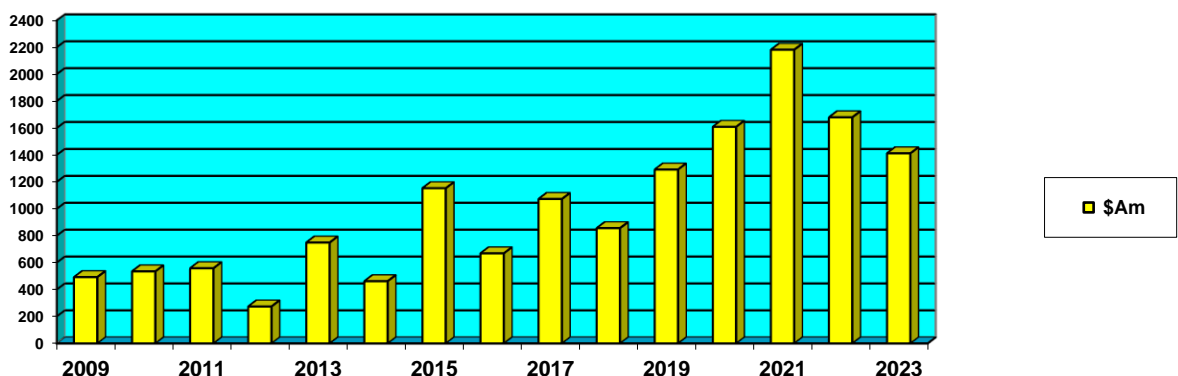
And before you could say “Summer holidays” it was December and the BDI-40 had bounced back 21 percent. To cap the year, December saw a flurry of excellent news, starting with Lee Rodne taking LTR Pharma to very successful IPO; Nancy Lurker and the Eyepoint team completing a successful phase II trial of Psivida’s Durasert for age-related macular oedema and raising \$350 million, the Volpara team announcing a \$296 million sale to Seoul’s Lunit, and Neuren posting statistically significant phase II results for NNZ-2591 for Phelan-McDermid syndrome. Congratulations to all.

Mentions in Dispatches

We can’t reach the finish line without a special mention of Vitura (formerly Cronos Australia) chief executive officer Rod Cocks and chief financial officer Tom Howitt for navigating the flak of certain large shareholders, while taking a marijuana company to the more serious world of tele-health – one of two companies to start in marijuana and move towards something more serious, rather than the other way around.

The other is Botanix, but Botanix back-doored into Bone Medical so it was a legitimate ASX-listed biotech before it jumped onto the Marijuana Bandwagon. Some time ago, it slid out of the grass and into drugs to treat excessive sweating. Nearing their FDA application, Botanix chair Vince Ippolito, chief executive officer Dr Howie McKibbon, executive director Matt Callahan and the inimitable Dr Stewart Washer deserve a special mention.

Capital Raisings 2009 -2024



While this year’s capital raising is the lowest since 2020 at \$1,412 million it’s far from doom and gloom. It is still the fourth best in 14 years.

“We’ll all be rooned,” they said. “Read the data,” we said.

2023 AWARDS

(Judges: David Langsam, Tim Boreham)

CEO OF THE YEAR

This was a very hard choice between several outstanding candidates.

Dr Sam Hupert and the team at Pro Medicus have had nothing short of another stellar year. So good, in fact, that the company is in danger of being promoted from the Biotech Daily Top-20 into the world of the Big Caps. It's \$9.2 billion market capitalization isn't far behind Cochlear's \$17.9 billion.

And Dr Chris Behrenbruch hasn't stopped Telix from running and running and not only earning massive revenues, but continually developing new products for the company's pipeline.

Then there are all the companies in the Biotech Daily lists that haven't gone belly-up in this year of struggle – and that has been Herculean in its own right. Everyone from LBT's Brent Barnes, Biotron's Dr Michelle Miller, Optiscan's Prof Camile Farah to Rhinomed's Michael Johnson and Uscom's Prof Rob Phillips.

Managing-director James McBrayer's perseverance with Cyclopharm to finally win FDA approval is nothing short of admirable, as is the FDA approval for the Compumedics team led by executive chair Prof David Burton.

But it is Neuren that has had the best year, in what Dr Brian McNamee once described as "In the glacial time periods of biotechnology, in 17 short years we have taken Gardasil [trofinetide] from lab bench to blockbuster" so former chief executive officer Dr Larry Glass, former chair Dr Richard Treagus and current chief executive officer Jon Pilcher all deserve the award.

The **2023 CEO of the Year** is shared by Dr Larry Glass and Jon Pilcher.

The **2023 Chair of the Year** (he was Neuren's chair until 2020) is Dr Richard Treagus.

The **2023 Kamikaze of the Year** was also hard fought.

Creso Pharma deserves the award simply for coming up with the meaningless name Melodiol, let alone its total failure to commercialize marijuana.

But MGC Pharma is up there as well - having taken its share price to less than one British farthing before fixing everything with a 1,000-to-one consolidation. The last time we looked the company was trading at 27 British pennies (51.1 cents), having backdoor listed into Erin Resources in 2016 at around 3.0 cents, with its current value around just over an English farthing (0.5 cents) in pre-consolidation money.

But there's worse. We had thought of including Bod Australia into Cannabis Corner but luckily it called in the administrators before we could. At least it wasn't trying to develop marijuana flavored beer like the famous Esense of blessed memory.

Hexima deserves a mention (see toe nail fungus above), as does Algorae which took Living Cell's xenotransplantation of pig Islets of Langerhans for type I diabetes and pig choroid brain cells for Parkinson's disease onto the marijuana-artificial intelligence bandwagon with an undisclosed second component.

But among the debris of failed companies and bad ideas, the year ended with ASIC releasing its findings on Adam Blumenthal, raising the profile of both his Everblu finance operation and the company he chaired and in which he invested - Creso Pharma (now Melodiol) - which posted a very lengthy ASX Aware Query last Friday that confirmed that nothing much has changed, other than the huge revenues from selling marijuana, aren't.

Summer holiday publishing schedule

Biotech Daily will shut down for the long, hot, Australian Summer from tomorrow and be back on deck refreshed and recharged on Monday January 22, 2024.

Australia is on holidays, so DO NOT put out any announcements - that no-one will read anyway - for the next month. Go to the beach.

That said, we monitor all announcements and publish a Summer Holiday Catch-Up edition, highlighting any companies posting bad news after the market closes on Christmas Eve and New Year's Eve.

Biotech Daily would like to thank its team of advisers: Prof George Fink, Dr Stuart Garrow, and Michael Ibbott for invaluable wisdom, insights and cautions throughout the year.

Biotech Daily thanks star columnists Tim Boreham and Peter Olszewski, and staff: Jamie Miller and Alex Langsam for all their superb work this year.

All errors through the year were the fault of the sacked sub-editors and none of the above.

We wish everyone an excellent Southern Hemisphere Summer break, Summer Solstice, Merry Christmas and Hogmanay/New Year and see you all in 2024.

David Langsam
Editor