

Biotech Daily



Thursday December 19, 2024

Daily news on ASX-listed biotechnology companies

2024 - The Year In Review

Despite all the naysayers, 2024 was brilliant for most biotechs, with a record year for raising capital (see below).

The Biotech Daily Top 40 Index (BDI-40) hit record highs throughout the year, more companies than ever posted revenue and some even had very unbiotechy profits.

A year of head down and hard work, with lots of financial reports and trial data. In fact, far too much data, with one or two companies letting us know every morsel of development. We think Nyrada posted the most pre-clinical data, but Immutep and Imugene confused readers with too much trial data. The announcements really should be the start of the trial and the results. A couple of paragraphs at the half-way mark and another couple when dosing has been completed. The Marrakesh Express also stops at every cow.

Volpara was acquired by Seoul's Lunit Inc for \$295.7 million, we lost Rhinomed from the ASX but the company continues. Medlab Clinical continues in suspension, we're not sure what's happening at Epsilon, and Auscann has been removed from the official list. Medical Grade Cannabis (MGC) changed its name to Argent and migrated to the London Stock Exchange at a market capitalization of \$46 million, spiking above \$300 million and is leaving the LSE currently valued at \$12 million.

Creso Pharma changed its name to Melodiol last year and disappeared altogether. Allegra was bought by shareholder and director Dr Nicholas Hartnell.

Anteris has listed on the Nasdaq. It's share price is an impressive \$9.00 but that follows a 10-to-one consolidation, followed by a 100-to-one consolidation, making the company worth 0.9 cents a share compared to the 17.0 cents at which it was trading in October 2014 when the then Admedus (previously Allied Medical and prior to that Biomed) appointed chair John Seaberg and managing-director Wayne Paterson as directors.

Hexima still exists, but terminated its deal with Real Thing Entertainment Pty Ltd. Perhaps production assistance by Ian 'Molly' Meldrum was required. IDT was going to be taken over by North Melbourne psychedelics company Myndbio, but that proved illusory.

Exopharm became Tryptamine. Regeneus became Cambium, retained its chief executive officer and did not much, at all. Cann Global was delisted by the ASX and some were not unhappy with the decision.

Percheron (formerly Antisense) had ATL1102 renamed as “avicursen” and Starpharma renamed its dendrimer enhanced product (DEP)-irinotecan as DEP-SN38. Pharmaxis became Syntara (not to be confused with either Cynata or Marc Sinatra).

Vitura sold nicotine vapes claiming they were ‘smoking cessation products’.

Too many Vales

The sad news was the large number of biotech-related deaths this year.

We deeply mourn several great losses, not least of which was our very own marijuana and psychedelics correspondent (Piotr) Peter Olszewski – the legendary JJ McRoach.

But the year started with the demise of major biotech investor Lang Walker and continued with luminaries including the doyen of Australian biotechnology, Leon Serry, along with Vectus chief executive officer Dr Karen Duggan, Qbiotics chair Dr Susan Foden and long-standing colleague and former Peptech and Arana chief executive officer Dr John Chiplin.

We also lost Nobel Laureate Dr (John) Robin Warren, who worked with Prof Barry Marshall in the discovery of the *Helicobacter pylori* bacterium.

A.I. & A.S.

Artificial intelligence – previously known as computer software – remained the biotech buzzword of the year with more companies claiming to be ‘A.I.-this’ or ‘A.I.-that’, having learnt how to program their computers.

But in the real world, we quickly discovered A.I.’s sibling A.S. through myriad programs. It’s called Artificial Stupidity - also known as GIGO: garbage in, garbage out.

February

Proteomics expanded from diabetic kidney disease detection to endometriosis and oesophageal cancer, Oncosil expanded its pancreatic cancer treatment to Türkiye and more German hospitals, the Federal and Victoria governments told us they were pouring millions of dollars into all sorts of medical research and commercialization, CSL clearly said the CSL112 cardiac trial missed its primary endpoint and dropped the program, but the next day announced record half year revenue and profit.

The US Food and Drug Administration refused Starpharma’s appeal to approve Vivagel BV for bacterial vaginosis maintaining the need for “additional clinical efficacy data” - in other words: another trial.

A number of companies took Endpoints Capital and Radium RDTI loans along with a raft of draw-down equity facilities. The best was Inhalerx with a market capitalization of \$6 million claiming it had an investment of \$30 million, which turned out to be a draw-down equity facility.

More mice showed that drugs worked for all sorts of cancers, including Race's bisantrene for acute myeloid leukaemia and Invion's INV043 curing 80 percent of mouse anal cancers. Mice also had improvements in heart conditions, vasculitis, sepsis, melanoma, psoriatic arthritis and Alzheimer's disease.

In April, Aegros said it hoped to raise \$100 million to become Australia's biggest blood fractionator (don't mention CSL) and last month Aegros executive chair Dr Hari Nair told Biotech Daily the company hoped to "complete a raise prior to Christmas".

Dr Nair also provided "a flat denial" to a question about Dr Esra Ogru working with Aegros.

There were persistent rumors that the convicted thief and former Phosphagenics chief executive officer Dr Ogru was working with some unnamed biotechs, but no one was boasting of her acquisition. And none were speaking "on the record".

Blinklab jumped 50 percent on its initial public offer, closing up 32.5 percent at 26.5 cents for its autism and neurological test.

Neurotech marijuana NT1164 met endpoints for autism and Rett syndrome, claiming the latter's 14-patient trial "compares favorably" with Neuren's 187-patient trial.

The Federal Court of Australia handed former Creso Pharma chair Adam Blumenthal a fine of \$850,000 and banned him from managing corporations for five years, following an Australian Securities and Investments Commission and Australian Federal Police investigation of his dealings as the chair of Everblu Capital and "alleging market rigging and breaches of his duties as a director" of Everblu and Creso.

Pharmaust replaced chief executive officer Dr Michael Thurn in April and after a complete changing of the guard, losing long-time chair Dr Roger Aston along with directors Rob Bishop, Dr Tom Duthy and a little later Sam Wright, Dr Thurn returned in May to rename the company Neurizon, turning Elanco's 'monepantel for sheep round worm' to the much snappier 'NUZ-001 for amyotrophic lateral sclerosis (ALS)'.

Ausbiotech appointed Rebekah Cassidy as its new chief executive officer and Bio-Melbourne appointed Ausbiotech's Karen Parr as its chief executive officer.

Nanosonics finally announced the FDA filing for its Coris endoscope cleaning system. In 2022, the company said it expected non-US approvals from the end of 2023 but gave no timeline for US approval. Cochlear completed its Oticon acquisition. Pro Medicus wrote a further \$45 million in five new Visage deals.

July

The first day of the new financial year began with the BDI-40 at an 18-year record high - up 847 percent over 18 years, compared to the ASX200 up 53 percent in the same time. Brandon Capital raised \$270 million for its Biotech Investment Fund VI. The next day Immutep said it had raised \$90 million, with \$10 million more to go. Radiopharm raised \$70 million. So much for the lack of venture capital.

Epsilon (previously The Hydroponics Company) founder Alan Beasley won the fight for the company but we're not sure what was meant to happen once he did.

Telix decided to waste a lot of time and effort listing on the Nasdaq and raising \$300 million, but pulled the plug eight days later (we could have told them, but no one listens).

The FDA approved Botanix Sofdra for underarm sweating, the TGA approved Control Bionics' Drove wheelchair module and Imricor conducted its first atrial flutter ablation.

Tryptamine dosed its first psilocybin patient, Patrys said PAT-DX1 testing was late, again, Mesoblast re-filed its application to the FDA for Ryoncil for paediatric graft versus host disease, for the third time, with FDA surprising everyone with today's approval..

In the US, Kazia had some good news from its Paxalisib brain cancer trial and jumped 248 percent to 98.8 cents. It's market capitalization reached \$35 million on December 1, 2024, a long way from the \$207 million in 2021 two years before it went to the Nasdaq for the better valuations of the more informed US punters.

Polynovo was the first to post record revenue for the year to June 30 "up 58 percent to \$105 million" and was far from the last. Telix raised a record \$650 million through convertible notes – possibly the biggest in Australian biotech outside the Big Caps.

Bivacor implanted its first artificial heart and although much of the work was done in the US, we still claim the Oneventures-backed company as one of ours.

Medadvisor, Micro-X and Cardiex posted record receipts from customers.

In August, for reasons we can't fathom, Israel's Redhill Biopharma, which bought Sydney's Giaconda in 2010, leapt 98 percent on six-year-old data. We don't begrudge them the uplift, but the data on Myoconda (RHB-104) for Crohn's disease was not new.

There is a general rule in Australian biotech: When a company releases good news, the share price goes down. When a company announces bad news, the share price goes down. When a company announces no news, the share price goes down. Occasionally, for no discernible reason, whatsoever, the share price goes up.

All four Big Caps - Cochlear, CSL, Pro Medicus and Resmed - posted revenue and profits up, probably all to record levels. Telix declared an H1 maiden profit, following the full year maiden profit for 2023.

Argent (MGC) said it would delist from the ASX, but by November had changed its mind and decided to stay on the ASX but delist from the LSE, while maintaining a presence on the US over-the-counter market.

And fewer companies than ever before still failed to comprehend the memo that their RDTI was not revenue. The message is getting through to most, but there are some that think their punters are truly stupid and won't read the P&L statement.

EBR filed its final module to the US Food and Drug Administration for its Wise heart pacing device, with a 'yay' hoped for soon in the new year.

Then something strange happened. Biotech Daily received an email from the Federal Takeovers Panel saying the matter of Tissue Therapies had been referred. It went nowhere - in itself - but founder and chief executive officer Tony Charara was the last person standing after the applicants to the Takeovers Panel failed and chair Jack Lowenstein and directors Brian Gray and Dr Michael Silberberg left the building.

In August, Bioxyne said it had an up-to \$28 million deal with an unnamed company to supply marijuana gummies, later telling the ASX it had no idea why its share price climbed 143 percent, other than the up-to \$28 million marijuana gummies deal. By mid-September, the ASX suspended Bioxyne for not providing specific information about the \$28 million marijuana gummies deal and a few days later Bioxyne fessed-up that the customer was the Melbourne and Berlin-based Montu Group Pty Ltd.

Woke added LSD to its mushroom psilocybin pipeline, making it one of the most trippy workplaces to be. And Patrys had more delays with PAT-DX1 manufacturing.

October began with two august bodies claiming that it was hard to raise funds for Australian biotech. Unfortunately for them, the facts were opposite. This year has been a record year for capital raisings (see chart and commentary below).

We are aware that some companies have struggled to raise funds and some have technologies we think deserve funding. But the truth is that of all the companies having difficulty raising money, many have drugs, devices, diagnostics or software that don't appear to be very interesting, benefit human health or are likely to make a buck (see the 2024 Kamikaze Award below).

Patrys gave up on PAT-DX1, refocussing on the full antibody PAT-DX3. Patrys chief executive officer Dr James Campbell said that both were anti-cancer and inflammatory molecules, but DX1 was smaller and "penetrated the blood-brain-barrier a bit better".

Then came the onslaught of pre-revenue companies thinking it a good idea to give directors and c-level staff options, shares, performance rights and restricted shares, before giving investors dividends.

We have tried to point out how foolhardy this is for nearly two decades, but not many are listening. Some of the best companies don't do it all. Some of the worst do it all the time. The most amusing are those who stick their noses in the trough when they already have a remuneration report first strike, but simply don't "get it".

November gave some interesting results.

Monash University did a lot of good work through the year, as did other universities and research institutes.

One of the best headlines we had the opportunity to write was that 'Psilocybin May Aid Depression, In Rats'. We don't know how one would begin to study that, but the next time we see a depressed rat, we'll send it mushroom foraging in the Dandenong Ranges or on Mt Macedon or as some sources we heard in a pub and would never recognise if we saw them again, officer, say: try Malvern Valley (Gardiner's Creek) or even along the Yarra.

The FDA approved Echo IQ's Echosolv for aortic stenosis, Prof Andrew Wilkes and Dr Chris Burns won the well-deserved \$250,000 Prime Minister's Prize for Innovation for inventing and commercializing Ojjara, previously known as momelotinib or CYT387, for myelofibrosis; and Ausbiotech ran its "biggest" conference and bio-invest summit, with Bivacor chief executive officer Dr Daniel Timms giving the Prof Nancy Millis Oration.

November kicked-off with the biggest change to the Biotech Daily Indices: Pro Medicus was promoted to the Big Caps, having overtaken Cochlear's market capitalization.

Always Remember the 5th of November

That used to be the slogan for Guy Fawkes Night – also known as Bonfire or Cracker Night. But this year it took on a whole new meaning as President Donald John Trump won a second US election and announced his new Health Czar as Robert Francis Kennedy Jr.

With a month to go to Inauguration Day, we have no idea whether Junior will be libertarian and let everything through the FDA, or continue his anti-science agenda, banning vaccines, removing fluoride from water and preventing anything passing the FDA.

According to the Washington Post, the new head of the FDA is Dr Marty Makary, a Johns Hopkins surgeon, with Republican representative and vaccine sceptic Dave Weldon running the Centres for Disease Control and Prevention. The Post said that Dr Janette Nesheiwat was a medical doctor chosen to be the next Surgeon General but was better known as a Fox News commentator.

And all report to Junior.

Back home, Neuren received \$76 million for its share of Acadia's sale of the Daybue (trofinetide) rare paediatric disease priority review voucher, which sold for \$US150 million (\$A227 million). This was separate from a \$76 million Daybue milestone payment. Bionomics soared 215 percent from 19 US cents to 60.5 US cents on news that it would be paid a \$1 million milestone by Adelaide's Carina Biotech, which just happens to be helmed by Bionomics former chief executive officer Dr Deborah Rathjen. Yesterday, the share price had fallen back to 26.2 US cents.

And then the opposition to directors' stock and remuneration reports began in earnest. The strongest vote against a remuneration report was Island with a 92 percent second strike and 98 percent board spill vote, but it wasn't on its own. Biotron not only copped a 55 percent first strike, it also lost two directors; Atomo won a 44 percent second strike; Rhythm earned a 42 percent first strike; Imugene and Percheron both had 35 percent first strikes (with Percheron withdrawing two resolutions); 4D Medical copped a 32 percent first strike; and Patrys a 30 percent first strike,

On November 20, Genetic Technologies appointed administrators. A long time coming and just eight days short of the 10th anniversary of founder Dr Mervyn Jacobson being sentenced to 12 months porridge (see below).

And before you could say "Summer holidays" it was December and the BDI-40 was at its 11th record high for the year. The only month it slipped was August.

Micro-X had a funny start to Summer having to tell the ASX that a US Government website had announced a \$12.75 million contract before sealing the deal; and the following day, formally announcing the contract.

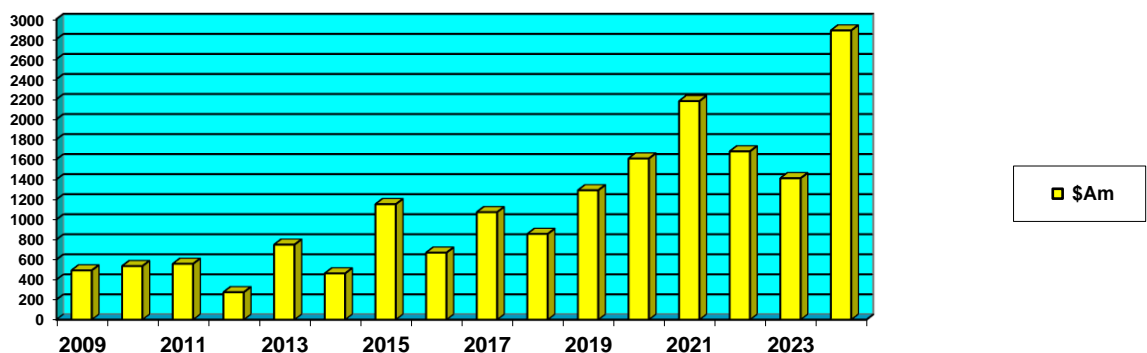
Nobel laureate Prof Gus Nossal donated an undisclosed “big wadge” of cash to The Walter and Eliza Hall Institute providing a perpetual professorship in his name. Given that professors are paid around \$180,000 a year, a perpetual donation would have to be at least \$2 million. We like Gus!

The Monash University-based Moderna mRNA vaccine factory was officially opened by the Federal and Victoria Governments. Anteris said it would redomicile in the US, pending a successful initial public offer, which it did. Pro Medicus founders Dr Sam Hupert and Anthony Hall sold one million Pro Medicus shares each at \$256.73 a share, having previously sold one million shares each at \$88.02 a share. Why didn't this writer buy shares at 70 cents each when he had the chance?

Visioneering asked the ASX to delist, having failed to commercialize its contact lenses and one biotech executive claimed companies were leaving the ASX and not listing due to excessive costs and corporate governance burdens. One problem facing the ASX is that in the absence of a proper regulator (the Australian Securities and Investments Commission is as useless as mammary glands on a male bovine), the ASX is both the de-facto regulator, and a fuddy-duddy gentleman stockbrokers' club. The year ended with Mesoblast climbing to a \$2 billion market capitalization before the news the FDA approved Ryoncil for GvHD. Anteris raised \$138 million to list on the Nasdaq, and Percheron very honestly reported that avicursen failed to improve Duchenne muscular dystrophy.

And in great news was missed by many who didn't understand its importance, Ghana approved Medicines Development for Global Health's moxidectin for river blindness. The US Food and Drug Administration approved the Melbourne-developed moxidectin in 2018, but the Ghana approval was for the first river blindness endemic country – meaning the drug will be rolled out and used as a treatment and preventative. Altogether an excellent result for the not-for-profit MDGH.

Capital Raisings 2009 -2024



This year's capital raising is the best on record at \$2,887 million. Far from doom and gloom, it has been an excellent year for biotechs.

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

2024 AWARDS

(Judges: David Langsam, Tim Boreham, Jamie Miller)

CEO OF THE YEAR

There are several serious candidates, but there was only one leader of the pack.

The runners up were Dr Chris Behrenbruch at Telix, Dr Alan Taylor at Clarity, Cyclopharm's James McBrayer, Compumedics Dr David Burton, Dimerix's Dr Nina Webster, Immutep's Marc Voigt and for sheer perseverance both Invion's Thian Chew and Oncosil's Nigel Lange.

As foreshadowed last year, Dr Sam Hupert and the team at Pro Medicus have forced Biotech Daily to promote them from the Biotech Daily Top-20 into the world of the Big Caps. It's \$27 billion market capitalization has exceeded Cochlear's.

The **2024 CEO of the Year** is Dr Sam Hupert and the team at Pro Medicus.

The **2024 Chair of the Year** has been with-held this year. We can't just keep on giving it to David Williams and Paul Hopper every year.

The **2024 Kamikaze of the Year** was also hard fought.

There were so many from which to choose.

It is true that marijuana companies dominated the race to the bottom, but for complete ineptitude the award has to go to Genetic Technologies, for taking a very good idea and failing to commercialize it.

A long time ago, before founder Dr Mervyn Jacobson went to gaol for a year for insider trading, Genetic Technologies did genetic testing and some speak very highly of that company.

But Dr Jacobson had set the course and sacking two good boards for not doing what they were told was just the beginning. The company then developed a so-called breast cancer test, which was more of a questionnaire, before revealing it had a new test that also worked for Black and Hispanic American women.

Hang on.

You never told us that the test was exclusively for White women.

But that wasn't the end. Instead of charging \$US4,000 including insurance reimbursement Genetic Technologies said it would sell the test directly to women ... for \$US200 a go. It was very hard to take the company seriously after that.

Finally, under the direction of chair Peter Rubinstein and chief executive officer Simon Morriss, Genetic Technologies has appointed administrators and is seeking relief from its financial obligations.

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 20, 2025.

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 columnist Tim Boreham and deputy editors, 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, Happy Chanukah and Hogmanay/New Year and see you all in 2025.

David Langsam
Editor