



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's A-To-Z Of 2024 Biotech

By **TIM BOREHAM**

From artificial intelligence (A.I.) to zygotes, the biotech sector this year delivered the A to Z of excitement, intrigue, occasional disappointment and downright disaster.

His virtual stethoscope on hand, Dr Boreham was on duty to diagnose every announcement (OK - almost every pronouncement), ranging from genuine regulatory approvals and commercial deals, to brazen attempts to spinning out failed trails.

The year started with deep pessimism but looks like ending with a powerful rally amid a flurry of trial results, approvals and – of course – capital raisings.

So, here's the towering year cut to alphabetic brevity:

A is for A.I., as in artificial intelligence, not artificial insemination. Only the bravest device and diagnostic plays don't purport to be using the tool – but there's a gaping chasm between real A.I. and tricked up humanoid intelligence known as 'algos' (algorithms).

Still, A.I. is radically automating surgical procedures. All the robots need to do is to perfect their golf swing and surgeons will be headed the way of facsimiles (still used in the pathology sector, by the way) and Sony Beta tapes.

B is for goodbye to Biden and probably most of his healthcare reforms including the ambitious Moonshot cancer eradication program.

B is for Bcal Diagnostics, which is on-track for a commercial launch of its blood-based breast cancer detection tool in early 2025.

B is also for the baloney about pending big-ticket partnerships and regulatory approvals that never happen, multi-billion dollar 'addressable markets' and failed trials morphing into successful ones with data mining.

C is for the culprits who know who they are.

C is for 'Cannabis corner' which has generally disappointed, but a standout among the weeds is Neurotech International with its proposed cannabinoid-based treatment for childhood neurological disorders.

C is also for a cascade of capital raisings. Many were small, admittedly, but Telix and Opthea blazed the way with raisings of \$650 million and \$220 million respectively.

D is for Dimerix, a sector winner on the back of two distribution deals that had front-end cash. We await the results of the company's phase III trial for the rare kidney disease focal segmental glomerulosclerosis (FSGS), due next year.

D is also for depression, not a reference to the US Democrats but clinical work on the part of Actinogen (depression and Alzheimer's), Trivarx (depression and sleep) and Avecho Biotechnology (pot).

E is for Emvision, which hopes to start a pivotal trial for its portable stroke detection unit by March next year.

F is for failure. In a year of soaring sectoral success, there are always casualties as well.

The private point-of-care diagnostics house Ellume called in the receivers in June, reportedly owing \$200 million to creditors. Genetic Technologies appointed voluntary administrators in November, after a capital raising fell well-short of the minimum \$2 million required.

In October, Patrys cancelled its lead DNA damage repair program, citing "manufacturing challenges" and in a rare setback, CSL axed its drug candidate for acute myocardial infarction? Missed its primary endpoint in an expansive – and expensive – trial.

Oh, **F**ruitcake!

G is for the great windfall for Neuren Pharmaceuticals, which last month pocketed \$US50 million from a one-third share of an FDA rare paediatric disease priority review voucher, and a similar amount in royalties from Daybue (trofinetide) sales.

G is also for Genetic Signatures, which won long-awaited FDA approval for its Easyscreen molecular test that detects eight gastro-intestinal parasites at once.

H is for 'hero' stock Pro Medicus, now valued at \$24 billion and worth more than the smallest of biotech's former Big Three, Cochlear. So, make that the biotech Big Four

I is for IPOs (and lack thereof)

Conditions remained subdued, but Blinklab (autism testing) joined the bourse in early April, breaking an eight-month drought, while Renerve (nerve repair) and Vitrafy (cryogenics) debuted last month.

I is for drug repurposer Island Pharmaceuticals and its quest to rid the world of the rapidly spreading, mosquito-borne dengue fever.

I is also for immune-oncology houses Immutep and Imugene and their steady stream of trial updates. The challenge is not to confuse the two companies and work out which trial is which, bearing in mind that neither has an approved therapy.

J is for janus kinase (JAK) inhibitor, which delivered its inventors, Prof Andrew Wilks and Dr Chris Burns, the \$250,000 Prime Minister's Prize for Innovation.

JAKs had their day in the sun when the FDA in late 2023 approved the locally developed JAK-based Ojjaara (mometotinib) for myelofibrosis.

Ojjaara was invented by the head of Amplia Therapeutics, Dr Burns and founder of the formerly ASX-listed Cytopia, Prof Wilks. And Prime Minister Anthony Albanese awarded the prize in October this year.

K is for Kamala – Kamala who?- and Kiwi companies.

The latter are key contributors to the ASX biotech sector, via the likes of Aroa Biosurgery and cervical cancer screener Truscreen, Pacific Edge and the overlooked Resmed rival Fisher & Paykel Health. Neuren also had NZ roots, while breast imager Volpara was taken over and delisted in May.

L is for leadership changes at more than a dozen companies, with a high female representation among incoming CEOs.

At Genetic Signatures, Allison Rossiter succeeded Dr John Melki.

At Impedimed, Dr Parmjot Bains took over from Richard Valencia.

At Somnomed, Karen Borg took over from Neil Verdal-Austin

At Chimeric Therapeutics, Jennifer Chow suddenly departed in favor of Dr Rebecca McQualter, while at Starpharma Cheryl Maley took over from Dr Jackie Fairley.

Going against the trend, at Opthea the US-based Dr Fred Guerard replaced founder Dr Megan Baldwin. At Cann Group, Peter Koetsier took over from Jenni Pilcher.

On April 23, Pharmaust (now Neurizon) announced the departure of CEO Dr Michael Thurn and his re-appointment on May 31 – surely the shortest resignation in biotech history.

At Vitura Health, Geoff Cockerill replaced Rodney Cocks, which poses the question: who will be responsible for the cock-ups?

M is for Making America Healthy Again by vilifying vaccines and established medical science.

M is also for stem cell developer Mesoblast, which has regained investor favor on expectations it will finally, finally win FDA approval (for paediatric graft-versus-host disease). D (decision) day is expected on or before January 7 next year.

N is for name change, with Pharmaust becoming Neurizon, Cronos Australia morphing into Vitura Health and Regeneus regenerating into Cambium Bio. MGC Pharmaceuticals became Argent Biopharma and LBT Innovations is now Clever Culture Systems.

Are the marketing moniker gurus wasting their time?

As James Garner, the head of Percheron (formerly Antisense Therapeutics) remarked: "You could call it Potato Therapeutics and it would just be the same."

N is also for Nasdaq, with Telix and Radiopharm pursuing secondary listings on the tech-heavy exchange. Late last year, Incannex Healthcare redomiciled to the Nasdaq and heart valve innovator Anteris Technologies plans to do so next year.

O is for the semaglutide injectable obesity drugs, best known as the branded Ozempic.

Their emergence has prompted speculation about reduced need for sleep apnoea aids (sorry, Resmed) and dialysis (sorry, CSL).

Is it really the end of what TV reporters breathlessly describe as 'obesity epidemic'?

We say **F**, as in Fat Chance.

O is also for Opthea, which has two extensive phase III trials for wet AMD, a leading cause of blindness.

We'll 'see' next year when the first results are out. They will be company making – or company breaking.

P is for the towering Pro Medicus, which continues to blitz the US radiology market within both 'sandstone' institutions and the private hospitals.

P is also for psychedelic therapies and the fortunes of dabblers Bioxyne, Tryptamine Therapeutics, Emyria and – on the periphery – Little Green Pharma.

The FDA is far from convinced – but new health czar Robert F Kennedy Junior is an ardent fan and any bureaucrat troubled by the science can either tune in or drop out.

Q is for 'quite impressive', as in the sector's outperformance relative to the broader market.

Q is also for 'quality' which sums up most of Australia's medical research.

Q also stands for 'quixotic', as in RFK Jr.

R is for Raygun, our break-dancing Olympian who made failure our biggest national attribute since Gallipoli.

R is for radio-therapies and diagnostics. The rise and rise of Telix is well documented, but Clarity Pharmaceuticals and Radiopharm have also emerged from the doldrums.

S is for share success. Companies chalking impressive share gains this year include the come-from-nowhere Invion, Clarity, Mesoblast, Polynovo, Actinogen, Genetic Signatures, Syntara and Immutep.

S is also for the slow-burn success of SDI, a supplier and exporter of dental consumables (notably filling materials) since 1972.

T is for Telix and Trump. But they've both had more than their fair share of airtime so we will give a mention to Truscreen – the only company we know that is targeting non-developed countries for its cervical cancer screening tool.

U is for unusual, a trait we would ascribe to Opyl's algorithmic tool that claims to predict the likelihood of a clinical trial succeeding. The company will start the 'world's first' biotech fund run by A.I., so we will soon see how this brave new world pans out.

V is for vaccines. We're going to be hearing a lot more about the V-word in the world of RFK Junior. Fortunately, his anti-vaccination stance is unlikely to affect any ASX-listed biotechs, apart from CSL at the periphery.

V is also for the US veterans' market, a healthcare system that rivals the size of Australia's. The sector is being targeted by lung imaging plays 4D Medical, Cyclopharm and Singular Health.

W is for the buzzing wound care space: Polynovo, Avita and the aforementioned Aroa are encroaching the US market one dressing at a time, although Next Science appears to have been left behind.

X is for (e)xiting companies: Volpara and Ellume aside, Rhinomed went private and Visioneering plans to do the same, while Allegra Medical Technologies was taken over by an entity associated with a director.

Argent Biopharma sought better fortunes on the London exchange but decided to stay here.

X is also for (e)xaggerated claims about the size of an addressable market and the scope of a new product to disrupt well-established technologies.

Y is for "yes" from the FDA for Botanix and its treatment for excessive sweating – a case of persistence and perspiration. It was also "yes" for Echo IQ and its aortic stenosis detection diagnostic which is – you've got it - A.I. based.

The agency also approved Orthocell's nerve repair cuff, Remplir while LTR Pharma is on the up-and-up after winning local consent for its Spontan erectile dysfunction nasal spray.

Z is also for zygote, “a diploid cell formed by the fusion of two haploid gametes during fertilization in eukaryotic organisms with sexual reproduction”.

Our coverage admittedly was zygote-free but if you haven't heard at least one new biotech term a year, it's been a wasted 12 months.

Z is for Zoo (see 'Trump Administration')

Z is also for zzzz and the quest to put the insomnia epidemic (that word again) to bed once and for all.

The long-standing Compumedics has an increasingly snazzy array of sleep diagnostic gizmos. Trivarx is exploring the link between bad sleep and depression.

Meanwhile, Avecho is running a phase III trial to prove that cannabinoids may cause drowsiness ... who would have thought?

Speaking of rest, Dr Boreham's Crucible is taking one. Jab another vial of Ozempic for a guilt-free festive season and have a great one.