



Biotech Daily

Thursday December 21, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NOVA EYE UP 8%; NEXT SCIENCE DOWN 8%**
- * **2023 - THE YEAR IN REVIEW**
- * **GENETIC SIGNATURES RAISES \$15.9m**
- * **LA TROBE UNI SPINS OUT ALLESENSE FOR NANOMSLIDE**
- * **UNIVERSAL BIOSENSORS: '\$1m DECEMBER SALES'**
- * **IMMUTEP: GERMAN REGULATOR BACKS PHASE III EFTI NSCLC TRIAL**
- * **BOTANIX RESUBMITS SOFDRA NDA WITH LEAFLET CHANGES**
- * **INHALERX TAKES \$546k RADIUM RDTI LOAN**
- * **MICRO-X TO RELEASE 51m VOLUNTARY ESCROW SHARES**

MARKET REPORT

The Australian stock market fell 0.45 percent on Thursday December 21, 2023 with the ASX200 down 33.8 points to 7,504.1 points.

Ten of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and two were untraded.

Nova Eye was the best, up one cent or 8.3 percent to 13 cents, with 702,303 shares traded. Clarity and Universal Biosensors were up five percent or more; Curvebeam climbed 4.4 percent; Opthea was up 3.3 percent; Antisense and Genetic Signatures rose more than two percent; Orthocell and Proteomics were up more than one percent; with Pro Medicus and Resmed up by less than one percent.

Next Science led the falls, down 2.5 cents or 7.9 percent to 29 cents, with 153,761 shares traded.

Impedimed and Resonance lost more than six percent; Actinogen fell 4.35 percent; Syntara was down 3.85 percent; Avita, Clinuvel, Dimerix, Nanosonics and Starpharma shed more than two percent; 4D Medical, Cochlear, Compumedics, Cyclopharm, Immutep, Mesoblast, Neuren and Polynovo were down more than one percent; with CSL, Medical Developments and Telix down by less than one percent.

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 was 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 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 a Hopper's Fee? And Prime Minister Anthony Albanese opened CSL's new headquarters in what was once 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 his first contact with FDA was 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 Oktoberfest 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 board spill machinations, with the other two directors signing ASX announcements as “the majority of the board” which is as true as “a 66.6 percent success rate” in a trial where only one of three mice died.

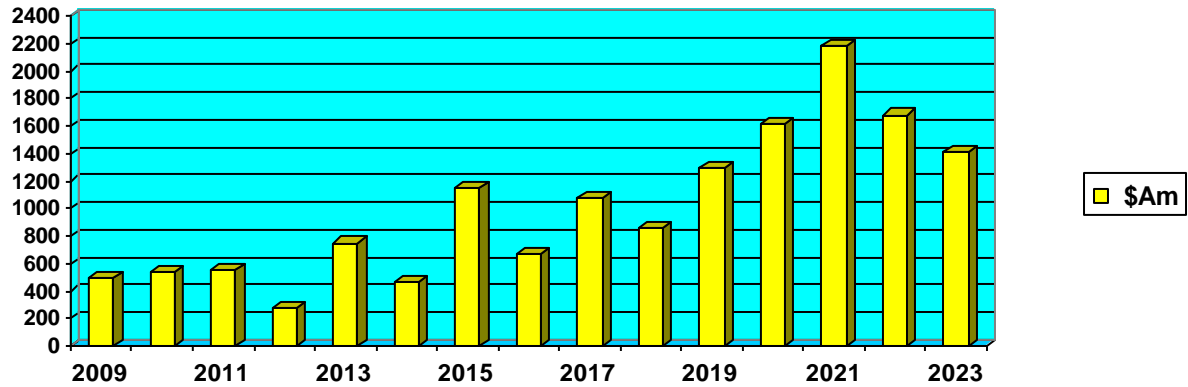
And before you could say “Summer holidays” it was December and the BDI-40 had bounced back 21 percent. To cap the year, Lee Rodne took LTR Pharma to a very successful IPO; Nancy Lurker and Eyepoint completed a successful phase II trial of Psivida’s Durasert for AMD and raised \$350 million, the Volpara team announced 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) chief executive officer Rod Cocks and chief financial officer Tom Howitt for navigating the flak of large shareholders, while taking a marijuana company to the 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 into drugs for excessive sweating. Filing their FDA re-application, Botanix chair Vince Ippolito, chief executive officer Dr Howie McKibbon, executive director Matt Callahan and the inimitable Dr Stewart Washer deserve a mention.

Capital Raisings 2009 -2023



While this year’s capital raising is the lowest since 2020, at \$1,412 million it’s far from doom and gloom - and 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 McBayer’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** (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 just over a pre-consolidation farthing.

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 a Hogmanay/New Year and see you all in 2024.

David Langsam
Editor

GENETIC SIGNATURES

Genetic Signatures says it has raised \$15.9 million through a \$7.96 million placement and a \$7.98 million fully-underwritten, one-for-6.65 rights issue, at 0.37 cents a share.

Genetic Signatures said the placement price was a 21.8 percent discount to the 15-day volume weighted average price, or a 15.9 percent discount to the last closing price.

The company said the rights issue had a record date of December 28, 2023, would open on January 2 and close on January 18, 2024.

Genetic Signatures said the funds would be used for additional regulatory approvals, customer installations, next-generation instrument development, product development as well as general working capital and the costs associated with the raise.

The company said Bell Potter Securities and Taylor Collision were joint lead managers to the capital raising and underwriters to the rights issue.

Genetic Signatures was up one cent or 2.3 percent to 45 cents.

LA TROBE UNIVERSITY, ALLESENSE PTY LTD

La Trobe University says its first major spin-out company Allesense will commercialize its Nanomslide microscope slide for identifying abnormal cells in suspect samples.

La Trobe said Nanomslide was a nano-fabricated coating on a glass microscope slide developed by researchers Prof Brian Abbey and Dr Eugeniu Balaur to identify abnormal cells in a sample using color contrast.

The University said its technology reduced identification time as it did not require dyes, and could be applied to any tissue, potentially helping to diagnose early stage and difficult-to-diagnose cancers, such as breast cancer.

La Trobe said the Allesense had been established after eight years of research on Nanomslide with the Peter MacCallum Cancer Centre and Sydney's Garvan Institute of Medical Research, with publication in the journal Nature in 2021 (BD: Oct 7, 2021).

The University said the development of Nanomslide was supported through its strategic innovation fund, which was "established to fast-track the translation of research findings into successful business ventures".

La Trobe said Ballarat's Welcome Ventures would invest \$2.5 million into Allesense, with Welcome Ventures' Julian Sutton appointed Allesense's managing-director.

The University said that Prof Abbey had received a \$2.9 million National Health and Medical Research Council investigator grant for Nanomslide research.

The University said Allesense was validating Nanomslide's manufacturing and quality management system with the Australian National Fabrication Facility, and that the Facility had purchased an instrument for proof-of-scale studies at its Melbourne-based centre.

La Trobe said Allesense would be located at the University's Bundoora campus and it expected the technology to be available for research use by the end of 2024.

Prof Abbey said that developing the Nanomslide was a career highlight and by commercializing the technology he hoped to be able to share it with the world.

"Being able to deliver this potentially life-changing technology to people around the world is very exciting," Prof Abbey said.

The Peter MacCallum Cancer Centre's co-inventor of Nanomslide Prof Belinda Parker had researched the Nanomslide in her laboratory for early-stage breast cancer detection.

"This technology has the potential to distinguish cancer cells from normal or benign cells in the breast, allowing accurate diagnosis at a very early stage," Prof Parker said.

"We are excited to test whether the Nanomslide also has potential in early diagnosis of a range of cancers" Prof Parker said.

Allesense is a private company.

UNIVERSAL BIOSENSORS

Universal Biosensors says it expects December sales to exceed \$1,000,000, with its largest order - 520 Xprexia Prime devices from India - to be delivered this year.

In the same announcement, Universal Biosensors said it expected the US Food and Drug Administration's decision regarding the approval of its Xprexia Prime blood coagulation monitoring devices by April 2024.

Universal Biosensors chief executive officer John Sharman said six of the company's 11 commercialized products had been on sale for about six months and increased sales in the six months to December 31, 2023 had been "strong" compared to the prior period.

"December is forecast to be Universal Biosensor's biggest revenue month ever and is the first time we expect to record \$1,000,000 from selling our products directly to customers, excluding Siemens," Mr Sharman said.

"We now have 11 revenue generating products in market and we are starting to build sales momentum," Mr Sharman said.

Universal Biosensors was up one cent or five percent to 21 cents

IMMUTEP

Immutep says it has "constructive feedback" from German regulator the Paul-Ehrlich Institut for its planned phase III trial of 'efti' for non-small cell lung cancer (NSCLC).

In May, Immutep said a 20-patient, investigator-led trial at the Frankfurt Institute of Clinical Cancer Research showed the combination of efti, or eftilagimod alpha, with anti-programmed cell death protein-1 (anti-PD-1) therapy and chemotherapy was well tolerated with "promising initial signals of efficacy" (BD: May 24, 2023).

In October, the company said a 114-patient phase II trial of efti with anti-programmed-death ligand-1 (PD-L1) therapy Keytruda, or pembrolizumab, for small cell lung cancer showed treatment led to a median overall survival rate of 35.5 months (BD: Oct 23, 2023).

Today, Immutep said the Institut was part of Germany's Committee for Medicinal Products for Human Use and was "supportive of Immutep moving into a registrational trial ... and evaluating efti in combination with an anti-PD-1 therapy" with or without chemotherapy. The company said the German regulator acknowledged the "good safety profile of efti in combination with anti-PD-1 therapy".

Immutep said it also discussed aspects of the trial design with the Institut, including selecting the control arm and the potential patient population, as defined by the level of PD-L1 expression.

The company did not state how many patients it expected in the trial.

Immutep said discussions with the US Food and Drug Administration, as well as other European regulators, stakeholders and potential partners, were ongoing, and that it expected to release its final trial design by April 2024.

Immutep chief executive officer Marc Voigt said the company appreciated "the valuable feedback ... and [we] look forward to additional discussions with other regulatory agencies in the coming months".

"Immutep is uniquely positioned to address multiple patient populations within non-small cell lung cancer as defined by their level of PD-L1 expression, including high, low, and negative expressers, with either efti combined with anti-PD-1 therapy or a triple combination approach including chemotherapy," Mr Voigt said.

"Our confidence in efti's ability in this important indication stems from the mature data in the large ...phase II trial, and the emerging data from the triple combination study," Mr Voigt said.

Immutep fell half a cent or 1.4 percent to 35 cents.

[BOTANIX PHARMACEUTICALS](#)

Botanix says it has resubmitted its new drug application (NDA) for sofpironium bromide gel, or Sofdra, for excessive sweating, to the US Food and Drug Administration.

In September, Botanix said the FDA denied its application, requesting printed 'instructions of use' changes "followed by another short human factors validation study before the NDA can be resubmitted"; and later the FDA approved it to resubmit the application (BD: Sep 26, Dec 4, 2023).

Today, the company said it had successfully completed its human factors validation study, in which all participants correctly prepared and applied the gel to their armpits.

Botanix said it would receive FDA confirmation that the resubmission constituted a "complete response" to its letter within 30 days and whether the review process would take six-months or, less-likely, two-months.

Botanix said it expected FDA approval by July 2024, with commercial preparations currently underway.

Botanix was unchanged at 16.5 cents with 8.75 million shares traded.

[INHALERX](#)

Inhalerx says it has taken a Radium Capital loan of \$545,830 against its expected Federal Government Research and Development Tax Incentive.

Inhalerx said the loan from Melbourne's Radium Capital was up-to the equivalent of 80 percent of its accrued research and development rebate for the period from January 1 to October 31, 2023.

The company said the initial advance of \$545,830 would allow it to continue its phase II ethics application for its marijuana-based IRX211 for acute episodic pain relief as well as an investigational new drug submission for its IRX616a with the US Food and Drug Administration.

Inhalerx was untraded at 2.9 cents.

[MICRO-X](#)

Micro-X says that it will release 50,709,000 shares from voluntary escrow on December 29, 2023.

Micro-X said it had a total of 518,064,117 shares on issue, as well as 27,462,589 performance rights and 650 convertible notes.

Micro-X was unchanged at 11 cents.