



# Biotech Daily

Thursday December 22, 2022

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: ONCOSIL UP 7%; USCOM DOWN 12%**
- \* **2022 - THE YEAR IN REVIEW**
- \* **PRO MEDICUS \$15m LUMINIS PACS CONTRACT**
- \* **NUHEARA PLACES \$3m, REALTEK TAKES \$1.5m**
- \* **AVECHO: ETHICS OKAY FOR PHASE III MARIJUANA INSOMNIA TRIAL**
- \* **CHIMERIC DOSES 3rd CLTX-CAR-T GLIOBLASTOMA STUDY COHORT**
- \* **OSTEOPORE \$1m PLACEMENT FOR SOUTH KOREAN DISTRIBUTORS**
- \* **IMRICOR \$2.2m NORTH DAKOTA INNOVATION FUND LOAN**
- \* **RACE \$804k FOR MD ANDERSON EXTRAMEDULLARY LEUKAEMIA TRIAL**
- \* **ACTINOGEN: FDA OKAYS 6 MONTHS XANAMEM PHASE IIb ALZHEIMER'S TRIAL**
- \* **CENTENARY \$996k NSW GRANT FOR COVID-19 NASAL VACCINE**
- \* **ANTEO TELLS ASX: 'WE HAVE MORE THAN 6 MONTHS CASH'**
- \* **OVENTUS RECAPITALIZATION 'DISCONTINUED'**
- \* **MARK, LINDA KERR, LINDMARK TAKE 8.2% OF CRYOSITE**
- \* **RICHARD MANN, ASSOCIATES BELOW 5% OF IMUGENE**
- \* **LISA DADSWELL REPLACES PAINCHEK CO SEC SALLY MCDOW**

## MARKET REPORT

The Australian stock market was up 0.53 percent on Thursday December 22, 2022, with the ASX200 up 37.4 points to 7,152.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and three were untraded. All Big Caps were up.

Oncosil was the best, up 0.3 cents or 6.8 percent to 4.7 cents, with 334,080 shares traded. Proteomics climbed six percent; Emvision was up five percent; Universal Biosensors improved 4.55 percent; Dimerix, Nanosonics, Pro Medicus and Telix were up more than three percent; Actinogen, Cochlear, Neuren and Polynovo rose more than two percent; CSL, Orthocell and Resonance were up more than one percent; with Avita, Clinuvel and Resmed up by less than one percent.

Uscom led the falls, down 0.6 cents or 12 percent to 4.4 cents, with 18,450 shares traded. Cyclopharm lost 7.2 percent; both Amplia and Kazia fell 5.3 percent; Atomo was down 3.6 percent; Next Science, Paradigm and Volpara shed more than two percent; Immutep, Impedimed and Opthea were down more than one percent; with Antisense and Mesoblast down by less than one percent.

## 2022 THE YEAR IN REVIEW

The Biotech Daily Top 40 Index (BDI-40) closed 2022 down 14.7 percent for the year to November 30, but recovering quite well from the mid-year low, over the last few months. The three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) were up 0.25 percent, with the benchmark ASX200 up 0.3 percent for the year to November 30.

It was a generally tougher year for Australian biotech with very few initial public offers compared to the large number in 2021.

Haemokinesis announced a \$17 million initial public offer (IPO) in March and then went very quiet. Dr Peter Molloy's Firebrick jumped 225 percent on its \$7 million IPO but hit regulatory hurdles, while Microba fell 28 percent on its \$30 million ASX April launch, but in November announced a partnership with Sonic pumping \$17.8 million into the company. Bionomics raised \$28 million to IPO on the Nasdaq in very late December last year, and was back at the well last month for a further \$7.7 million.

### **Heads down, nose to the grindstone**

Following two years of lockdowns and with the global markets in turmoil due to the pandemic, pandemic-induced supply chain delays and Russian President Vladimir Putin's invasion of Ukraine, most companies chose to work rather than market themselves or make unnecessary announcements. During the year, some chief executive officers and companies did venture out, but it was much lower key than in previous years.

This writer met three or four companies in 2022, compared to about one a week before The Virus. A dose of Covid-19 in June reinforced this gregarious extrovert's inner hermit.

Biotech Daily's year included a website revamp and we gratefully acknowledge the skills of Cristian Rojas at Redbox Designs and VGI Health's Dr Glenn Tong for the referral. With the Biotech Daily chief technology executive suitably retrained via Zoom and emails, the website is more attractive and is easier to upload. Next mission: the 2023 email system.

### **Summer**

The New Year started on the first day of our Summer break.

In very late December, the US Food and Drug Administration approved the Telix Illucix kit for prostate cancer imaging, which led to the company's first significant sales amounting to \$22.5 million in the three months to June 30.

Respiri began a series of deals for clinics and companies to use its Wheezo asthma detector, and just about everyone announced the start of a trial or a stage of recruitment. In previous years, initiating a phase I or II trial or reaching 50 percent recruitment was very significant news, but with the maturation of the Australian biotechnology sector, phase III or pivotal trial results and regulator approvals are the big news.

Dr Gisela Mautner replaced Noxopharm chief executive officer Dr Graham Kelly, who appeared to be taking a break from biotech. In late November, he resurfaced with Filamon Limited to raise \$3 million for a prostate cancer therapy. And Stemcell United, with Chinese herbal medicines, having eschewed stem cells and medical marijuana, extended its joint venture suspension.

Eleven of the 22 companies were removed from Cannabis Corner, most of them just growing or selling dope or hype and one – Little Green Pharma – confounded us with a phase III cannabidiol (CBD) sleep trial.

Memphasys had its first commercial sale of its Felix sperm separator and Universal Biosensors launched its wine acid test, Telix raised about \$200 million, Paradigm copped a second remuneration report strike – possibly related to the widespread practice of doling out shares and options to directors before paying shareholders dividends. There were numerous examples much later in the year in the November AGM season. Stuart Dignam replaced MTP Connect chief executive officer Dr Dan Grant.

“Wellness” collided with real medical research in February with Biome Australia touting a 55-patient subset of a 114-patient trial showing its probiotic reduced acne better than placebo. What Biome forgot to say was the trial was run by the unrelated Milan-based Giuliana SpA, and its probiotic was better. This didn’t help companies like Prota Therapeutics which is working on peanut allergies and Microba which analyzes gut microbiome to detect missing probiotics and might be of real use to human health.

CSL’s share plan raised \$750 million taking the total raised for its Vifor Pharma acquisition more than \$7 billion - proving just how terrible market conditions were; and Invictus said it would demerge from VGI Health, formerly Azure, formerly Invictus. CSL and Resmed posted record half year revenue and small biotechs continued to claim the Federal R&D Tax Incentive as “revenue” as if the only reason they existed was to spend investors’ money to earn taxpayer grants. Oh, and cure (or not) cancer, arthritis or toenail fungus.

Woke added lysergic acid diethylamide (LSD) to its magic mushroom portfolio and Emyria continued its work on MDMA (Ecstasy) analogs. Japan approved Avita’s Recell spray-on skin for burns, Lucy Turnbull returned to Immutep and Mesoblast lost Donal O’Dwyer who continued at Fisher & Paykel.

### **Autumn (tr: Australian fall)**

The season opened with the BDI-40 falling 12 percent and Firebrick began its appeal against the Australian Therapeutic Goods Administration (TGA) knock-back of its Nasodine anti-viral nasal spray, while Starpharma said its Viraleze anti-viral nasal spray’s active ingredient SPL7013 killed 95 percent of the Omicron variant of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) in one minute.

Avecho (formerly Phosphagenics) ran a 15-patient trial of marijuana cannabidiol (CBD) with its tocopheryl phosphate mixture (TPM) for osteoarthritis and claimed “highly significant” results for osteoarthritis pain reduction. Palla Pharma went into liquidation with “nothing for investors” showing that even opiate dealers can fail, but Incannex said its marijuana-based IHL-42X reduced sleep apnoea by 44 percent in an 11-patient trial.

Clinuvel's afamelanotide, earning revenue for photo-toxic skin complaints, showed safety and early efficacy for stroke in five of six patients, and Haemokinesis said it would raise \$17 million for a quick and simple blood group test and then went very quiet. Micro-X sent four mobile x-ray units to Ukraine and 4D Medical launched its XV lung scanner.

There was much discussion of mRNA vaccines for Sars-Cov-2 and other indications, with the Federal, Victoria and New South Wales governments providing funding, but IDT lost out. Despite a remarkable Pfizer-built stainless steel and glass drug manufacturing building, the company couldn't cross the line to be Australia's first mRNA manufacturer, with Victoria sealing a deal with Moderna for a new establishment at Monash University.

Microba fell on its "successful" \$30 million IPO raise at 45 cents a share. It appears that an unnamed institution or two might be jumping ship for a quick profit.

Pfizer offered \$100 million for Resapp's mobile phone software to differentiate respiratory illnesses, including Covid-19. Eventually, Resapp shareholders approved the deal but at the better price of \$179 million. Given that the company had not proven the test's accuracy, definitively, it was surprising to hear that investors were unhappy with the offer. Industry skeptics doubted that Resapp was worth \$100 million, let alone \$179 million. Hearty congratulations to Dr Tony Keating, Brian Leedman and the team.

Oncosil sold its first European pancreatic cancer radiation device, Osteopore had its first cranial implant sales in Spain, Teri Thomas replaced Volpara CEO Dr Richard Highnam, improving the percentage of women leading BDI-40 companies from 12.5 percent (five) to 15 percent (six). Stuart Dignam was confirmed as CEO of MTP Connect, Queensland's Protagonist tumbled on the Nasdaq following repeated drug setbacks, Cochlear began its \$170 million bid for Denmark's Oticon, running into concerns over market domination, and many companies showed that their drugs were safe and well-tolerated in early-stage trials.

Cannabis Corner was particularly good at showing that low-dose potentially over-the-counter cannabidiol (CBD) was safe and well tolerated, but there wasn't much evidence for efficacy, despite the popularity. There is a view that medical marijuana needs some tetrahydrocannabinol (THC) or a stronger dose of CBD or both. What is really needed ... draws breath ... for the umpteenth time ... are large, randomized, controlled trials.

Biotron's BIT225 killed Sars-Cov-2 in mice, and many others showed they could kill all sorts of things in mice (and Petri dishes), not least, the mice. LBT sold more Apas units but Osprey had funding issues. Alcidion, Polynovo, Pro Medicus and Volpara announced sales and revenue.

The Burnet Institute and Moderna partnered for mRNA vaccines, the CSIRO was awarded a psychedelics licence and the major cancer drug companies: Immutep, Imugene, Kazia and Prescient continued to confuse the Biotech Daily editorial team with an array of trials, trial names, drugs and cancers, with Clarity and Telix also trialing an array of radio-diagnostics and therapies for multiple cancers.

After a battering of medical research grant announcements from the previous Federal Government, we had the May 21 election and the War on China entered a ceasefire.

The main benefit of the Albanese Labor Government so far has been the easing of hostilities with our number one trading partner. Biotech Daily has published announcements and has heard private reports that the authorities in the People's Republic of China are making life a little easier for Australian biotech. The new Government announced a \$15 billion National Reconstruction Fund, with biotech and medical research one of seven areas of focus.

Starpharma finally won a battle with the TGA to have Viraleze reclassified as a medical device rather than a drug. The nasal spray does not enter the blood-stream, but sits in the nasal cavity killing bugs. Firebrick's fight continues.

## Winter

Prime Minister Anthony Albanese appointed Mark Butler as the Health and Aged Care Minister, with 'head geek' Ed Husic appointed the Minister for Industry and Science. While a Minister for Innovation was missing from the list, at least we have a Minister for Science.

Cann Group harvested its first crop at the top-secret Mildura facility and then one night someone left the shutters open and "a mysterious pink glow" emanated across the Mallee skies. No, it wasn't aliens or chemtrails or a secret Government vaccine experiment, just good old-fashioned marijuana grow-lamps.

Zelira said its marijuana Zenivol reduced the severity of insomnia, Oventus went into voluntary administration. Mesoblast said it would "vigorously defend" itself against a class action relating to announcements and its share price; and MGC claimed its marijuana could kill glioblastoma in cell lines. Zelira terminated its Health House deal which would later be taken up by Creso, resulting in a complicated repayment and purchase system.

Imugene climbed 48.5 percent on a claim that its 36-patient, phase II trial of HER-Vaxx for gastric cancer was statistically significant ( $p = 0.066$ ). But it used a "one-tailed" p-value, assuming there could only be benefit and no disbenefit. The one-tailed p-value of 0.066 translates to the more usual two-tailed p-value of 0.132, but the share price went up, so what would we know?

By June 30, the BDI-40 was down 37.6 percent for the Australian financial year, while the ASX200 only fell 10.2 percent and the three Big Caps of Cochlear, CSL and Resmed (which are not included in the BDI-40) fell 3.3 percent, so what would we know, again?

Former Opthea chief financial officer Mike Tonroe lasted a bit over a year at Genetic Technologies. And then Mike resurfaced at Imugene.

Hexima said it was winding up after failing to show its HXP124 had efficacy for toe nail fungus, the US FDA knocked back the Lumos Febridx diagnostic to differentiate bacterial from viral infections, MGC claimed its 150-patient, non-randomized, non-controlled, open-label trial of Artemic showed "statistically significant" efficacy for long-Covid but failed to provide specific data, while publishing graphs showing improvement over a six-week course of the *Boswellia serrata*, *Curcuma longa* and vitamin C-based food supplement.

Rhinomed said it would supply more than 10 million Rhinoswabs to Surescreen Australia for its respiratory tests with the potential to earn more than \$6.0 million, while Zelira had an interesting exchange with the ASX over share price movements.

Ancila Desai continued the biotech musical CFOs game, leaving IDT and reappearing a few days later at Medadvisor. Epsilon began its own musical chairs, with Steven Xu replacing CEO Jarrod White and later replaced by Josh Cui, and Polynovo appointed the Florida-based Swami Raote as its CEO.

Biotech Daily reminded companies that their Federal R&D Tax Incentive was not revenue.

The BDI-40 climbed 26.4 percent in July, making up most of its lost ground, but August 1 was also the day that Kazia announced the bad news that paxalisib did not meet the pre-defined criteria for continuing its “primary path to market” for glioblastoma. This was very disappointing for Kazia and the Australian biotech community. Paxalisib had been considered one of the more serious prospects for cancer and the company has been included in the BDI-40 for a long time. The good news is that CEO Dr James Garner says there are seven other paxalisib trials underway with interim or final results – including a pivotal trial - expected during 2023.

Proteomics claimed proof-of-concept for an endometriosis test and IQ3’s administrators said that even a deed of company arrangement would give “no return to shareholders”.

CSL announced it had Vifor in its sights, Lumos appealed the FDA Febridx knock-back, and Zelira continued its awareness discussions with the ASX. Mayne had a market capitalization of \$617.5 million on the day it sold its Metrics division for \$679 million to New Jersey’s Catalent, having acquired it in 2012 for around \$100 million. Biotech Daily was unsure whether its calculator needed a new battery or it read the media release incorrectly, given that the stock market is always right.

Opthea’s \$371 million raise was the year’s biggest - apart from CSL’s \$7 billion for Vifor, while Dr Andrew Forrest invested \$250 million in his Tenmile Health Technology Fund.

Woke said it would try its stronger WP002 psilocybin for “prolonged grief” which was listed, controversially, as a medical condition in the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5) in March.

At the end of the reporting season, a number of companies announced capital raises, while Pro Medicus said revenue was up 38 percent to \$93.5 million with profit up 44 percent to \$44 million. Telix posted first half revenue up 730 percent to \$24 million, Probiotec lifted its revenue 51 percent to \$182 million and profit by 170 percent to \$14 million. Clinuvel, Compumedics, Control Bionics, Cronos, Microba, Next Science, Polynovo, Rhinomed and Starpharma and all reported significant revenue increases.

And yet again, we had to explain to accountants and auditors that the Federal Government grant called the Research and Development Tax Incentive is not income unless your company’s role on the ASX is merely to raise money, pay directors and staff and claim the RDTI – which we suspect is the case with some companies.

## Spring

Spring cleaning saw an unusual number of senior comings and goings.

Dr Chris Burns replaced Amplia's Dr John Lambert, Auscann said it would lose Layton Mills, Living Cell had a board spill call but resolved the conflict before the meeting, Control Bionics lost Rob Wong to ill health, IDT lost Dr David Sparling, Oncosil re-gained founder Brian Leedman, two Cannabis Doctors Australia founders called for a Cronos board spill which fizzled out; Epsilon re-appointed Alan Beasley and lost both Patrick and Steven Xu, gaining Josh Cui, while biotech veteran Max Johnston retired from Medical Developments, with director James Corbett replacing Avita CEO Dr Mike Perry on just under \$1m a year.

In non-personnel news, an ethics committee blocked Neuroscientific's Emtinb trial citing safety, purity and efficacy, but that led to managing-director Matt Liddelow's resignation, Perth's Merchant Group became substantial in Hexima. Anton Chekhov said: "If there's a gun on the wall in act one, scene one, you must fire the gun by act three, scene two."

Ellume went into voluntary administration following its US recall of its Sars-Cov-2 rapid antigen tests and Anteo emerged as a creditor owed \$123,000.

Brandon opened a London office to raise funds for UK companies and the FDA rejected the Lumos Febridx appeal. Polynovo claimed "record" first quarter sales of \$12.5 million for its Novosorb wound repair, Dr Beata Edling replaced CEO Juliet Hull at Truscreen, the Bio-Melbourne Network launched its 'Wilam' meeting space, IDT announced board renewal, and Creso needed two new directors to replace former chair Adam Blumenthal, saying it would change its name to the completely unrelated Melodial Global Health to "assist in best capturing the essence of the diversified operations of the group".

Genetic Technologies appointed yet another veteran of the industry as chief financial officer and company secretary – this time Tony Di Pietro.

Canada approved Telix's Illucix for prostate cancer imaging, with first quarter revenue of \$55.3 million, Cronos posted record first quarter marijuana revenue of \$26 million, as we headed into AGM season and companies throwing shares, options and "performance" rights around like confetti at a wedding. Some of the performance rights hurdles were so high that directors needed to still be with the company to receive them.

Some of the options were "in the money". Some of the companies were knocked back, most weren't, but many had sufficient dissent to requisition extraordinary general meetings. If you are not paying dividends why should directors be awarded millions of shares, rights or options? In some cases, the companies were going backwards and still shelling-out stock. A few companies honorably said they were issuing stock in lieu of cash.

Founding CEO Robert Read announced his departure from Medadvisor, to be replaced by the US based Kevin Hutchison and Canada approved Polynovo's Novosorb BTM.

The first Federal Labor Budget had little directly affecting biotech in the short term, but a range of measures improving the quality-of-life for all staff, as well as the big promise of the \$15 billion infrastructure fund with medical research one of the areas of focus.

Neurotech claimed that at 20 weeks, a 14-patient, phase I/II trial of its marijuana NTI164 showed “statistically significant efficacy” in children with autism. A larger trial is planned.

November opened with the BDI-40 continuing to climb above the pre-Covid record high, but well below the 2021 bio-bubble when everyone claimed they had a test, treatment or cure for Covid. But the things that your liable, to read on the ASX, ain't necessarily so.

CSL paid \$US200 million to San Diego's Arcturus Therapeutics to licence its self-amplifying mRNA vaccine technology, Truscreen won Vietnam approvals, Anteo pulled the plug on its European Sars-Cov-2 diagnostic trial to focus on other point-of-care tests and Sue MacLeman announced she was vacating the chair at MTP Connect.

For Biotech Daily's 17<sup>th</sup> Birthday on November 7, Telix said its phase III TLX250-CDx renal cancer trial met its primary and “key secondary” endpoints, Cronos said it had been profitable for so long that the ASX no longer required quarterly reports and we believe that IDT was the first of many companies to withdraw a resolution to allow virtual-only meetings. While virtual meetings might save a lot of money, there are enough old-fashioned investors who want their sandwiches and cups of tea to keep companies holding face-to-face meetings, where pesky investors can ask questions.

Vaxxas made headlines by starting its phase I “needle-free” Sars-Cov-2 vaccine trial, Avita released new data showing that it hit a previously missed non-inferiority endpoint for Recell spray-on skin for soft tissue reconstruction, the privately-owned Que Oncology said its 131-patient trial showed that non-hormonal Q-122 reduced hot flushes and night sweats in women with breast cancer and the University of Queensland renamed the Diamantina Institute ‘The Frazer Institute’ to honor Gardasil inventor Prof Ian Frazer.

Mark Diamond announced his departure from Antisense ending his hold on the title of longest serving CEO in biotech. We're not sure who is next in line – Prof Silviu Itescu and Dr Michelle Miller are two that jump to mind with Prof David Burton, Prof Rob Phillips and Dr Sam Hupert also in the mix.

Then the AGM results came-in with remuneration report strikes and strong opposition to virtual meetings as well as directors shares and options.

The FDA approved CSL and Uniqure's Hemgenix - the first gene therapy for haemophilia B, with a US price tag of \$US3.5 million, leaving many to wonder who could afford it. Aroa's first half revenue was up 63 percent to \$27 million turning a previous loss to a \$1.5 million profit, Sonic said it would take 19.99 percent of Microba for \$17.8 million, Impedimed named Richard Valencia as its \$671,000 managing-director, and a Mater Research and University of Queensland study found no benefit for cancer pain from low dose cannabidiol (CBD) – the sort companies hope to have approved as over-the-counter treatments. The trial will look at higher doses and including tetrahydrocannabinol (THC).

Creso's James Ellingford, who calls himself “Dr” despite the absence of any recognised qualification, was the focus of newspaper reports for matters beyond the ASX and was bailed on six charges in late November.

Mr Ellingford was replaced at Creso but it took another week for him to leave Roots, which is not a wombat joke.



## Summer

Perth's Merchant Group removed the gun from the wall and called a Hexima board spill meeting adding the Sydney-based Race Oncology executive director Dr Daniel Tillett to the call. Hexima played hard ball by calling a face-to-face meeting in Melbourne. Cronos sold its millionth medical marijuana unit, with record \$10.7 million one month revenue, Vaxxas raised \$34 million and Cogstate joined Cronos being freed from Appendix 4Cs. The UK was concerned with Cochlear's Oticon takeover and Sue MacLeman left Anantara.

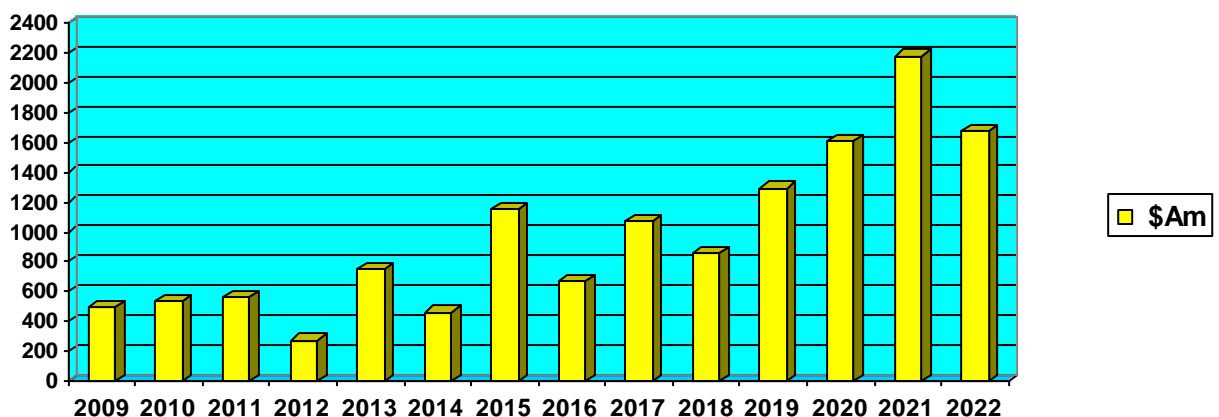
Queensland's Hough Consolidated Pty Ltd proposed to buy Ellume for \$US38 million (\$A56.2 million) and the Ellume creditors voted for something over nothing. Easy call.

CSL chief operating officer Dr Paul McKenzie was appointed a director to replace managing-director Paul Perreault in March, on \$2,590,000 a year, with huge incentives, Indonesia approved Starpharma's Viraleze anti-viral nasal spray and the Victorian Government launched the \$20 million 'Equity Investment Attraction Fund' for start-ups. Synchron raised \$110 million for its Switch brain-implanted computer interface, with funds from Bill Gates and Jeff Bezos, Polynovo's \$17 million share plan had \$35.27 million in applications and it increased the plan to \$20 million, taking the total raised to \$53 million.

Last Friday, Bionomics appointed Dr Spyridon Papapetropoulos as its CEO on \$826,476 a year and on Monday, confirmed that BNC210 failed to meet its endpoints for social anxiety disorder but "exhibited trends towards improvements" - similar to results for the other trials of BNC210 for post-traumatic stress disorder and agitation.

CSL had a positive European opinion for Hemgenix, LBT appointed Thermo Fisher Scientific its Apas Europe distributor, ending the Beckman Coulter contract, and the next day had a \$601,000 Thermo Fisher Apas module deal; Tenmile co-invested \$30 million with Brandon Capital in Aravax for a peanut allergy treatment and Woke said it would trial 25mg psilocybin for "prolonged grief" and "muscular-skeletal pain".

## Capital Raisings 2009 -2022



It's hard to comprehend the biotech doomsayers. While it's true that capital raisings fell 23.0 percent from last year's record high of \$2,182 million to only \$1,680 million at the time of writing, that figure is still higher than any other year and our second best on record, and does not include the CSL \$7.05 billion for Vifor. "We'll all be runed," they said. "Read the data," we said.

## **2022 AWARDS**

**(Judges: David Langsam, Tim Boreham)**

### **Chair of the Year**

This award is for those admirals of the fleet who give strategic directions to the captains of their ships. If the objective is unclear, the mission will fail.

The best-known people chairing several different Australian biotechnology companies are David Williams and Paul Hopper and both have won this particular gong.

Contenders are Dr Paul MacLeman who is the chair of the early-stage Adalta and Island, as well as the unlisted Drawbridge Pharmaceuticals, and Paradigm chair Paul Rennie who is yet to have success with that company while joining the recovery at Neuroscientific.

Maurie Stang has resigned as the two-decade chair of Nanosonics, having overseen the transition from research and development to commercialization and is currently deputy chair of Vectus Biosystems, as well as chair of Aeris Environmental, Lumitron Technologies and Henry Schein Dental. Congratulations Maurie Stang.

### **CEO of the Year**

As always, the competition has been fierce. The sector has achieved huge goals this year, with Clinuvel, Cronos, Polynovo and Pro Medicus just the ones that spring to mind with very significant revenues. We note the excellent work of Alcidion's Kate Quirke, Micro-X's Peter Rowland, Neuren's Jon Pilcher, Opthea's Dr Megan Baldwin, Proteomics' Dr Richard Lipscombe, Resapp's Dr Tony Keating and Rhythm's Glenn Gilbert. Telix's Dr Chris Behrenbruch was the front-runner having taken Illucix to multi-million-dollar sales. But the 2022 CEO of the Year is jointly awarded to Antisense's Mark Diamond and Rhinomed's Michael Johnson. Both have worked tirelessly. Michael Johnson found an application for nasal dilators that returns revenue, and Mark Diamond just about brought ATL1102 to the end of its pivotal trials as he retires as the longest-serving biotech CEO.

### **Kamikaze of the Year**

The Kamikaze award goes to companies that have flown themselves into the ground while aiming at other targets.

Despite Epsilon clearing out its board and management and not knowing what to do with itself, Zelira turning into something confusing, adding food additives to its marijuana play. Several companies struggled through the year and we appear to have lost Osprey, with Oventus and Ellume in administration with some hope.

The clear winner for appointing and losing chairs Adam Blumenthal and James Ellingford, not to mention suffering collateral damage from an ASIC inquiry should be Creso Pharma, but there were actually companies that died altogether, including Palla Pharma.

The Kamikaze of 2022 is the formerly Dr George Syrmalis-run IQ3 in administration, sans luxury yachts and an investigation into other accounting measures.

## Summer holiday publishing schedule

Biotech Daily will shut down for the long, hot, Australian Summer from today and be back on deck refreshed and recharged on Monday January 23, 2023.

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: Noah Nicholas, James Costa 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, Happy Channukah, Merry Christmas, Summer Solstice and Hogmanay/New Year and see you all in 2023.

**David Langsam**  
**Editor**

## [PRO MEDICUS](#)

Pro Medicus says its wholly-owned subsidiary, Visage Imaging has a seven-year, \$15 million contract with Luminis Health for its picture archive communication system (PACS). Pro Medicus said that the Annapolis, Maryland-based Luminis Health, was a not-for-profit integrated delivery network which operated in central Maryland, from Washington DC, to Delaware.

The company said that Visage would implement its cloud-engineered Visage 7 enterprise imaging platform, including its open archive and workflow modules, across Luminis' network "immediately" with the platform to launch by July 2023.

Pro Medicus chief executive officer Dr Sam Hupert said that integrated delivery networks (IDNs) "constitute the largest market segment in North America and we continue to build momentum in this segment with this, our fourth material IDN contract in the last 12 months".

"It also serves to highlight that our solution is equally well suited to mid-sized IDNs as it is to the large ones, confirming our view that our total addressable market in the IDN space is very significant," Dr Hupert said.

"Our pipeline remains strong and spans all market segments, with accelerating interest in cloud," Dr Hupert said.

Over the past two years, all the new healthcare institutions we have signed have chosen a fully [internet] cloud-based implementation of Visage 7 and in the case of Luminis Health it is our "full-stack" comprising all three products namely viewer, workflow and archive, a trend we believe we will see a lot more of," Dr Hupert said.

Pro Medicus was up \$2.12 or 3.9 percent to \$56.40 with 274,337 shares traded.

## [NUHEARA](#)

Nuheara says it has “firm commitments” for \$3 million in a placement at 18 cents a share, “cornerstoned” by \$1.5 million from Taiwan’s Realtek Semiconductor Corp.

Nuheara said the price was a 25 percent discount to the last traded price, and a 17.9 percent discount to the five-day volume-weighted average price to December 20, 2022.

The company said that Realtek was an existing investor who had previously subscribed for \$4.2 million in placements and convertible note issues (BD: Jul 1, Sep 8, 2022).

Nuheara said that Sydney’s Petra Capital was lead managing and bookrunner to the placement, with Automic Markets acting as corporate advisor.

Nuheara managing-director Justin Miller said the funds would help “ramp-up production for the over-the-counter roll-out of our US FDA cleared hearing aids in the US”.

Nuheara fell 1.5 cents or 2.3 percent to 65 cents.

## [AVECHO BIOTECHNOLOGY](#)

Avecho says it has ethics approval for its 540-patient pivotal, phase III trial of its oral marijuana-based cannabidiol (CBD) ‘softgel’ capsule for insomnia, to begin in 2023.

In 2021, Avecho said it had a pre-submission meeting with the Australian Therapeutic Goods Administration for its over-the-counter soft-gel cannabidiol product for insomnia, and would address design aspects of a pivotal phase III trial and safety information related to cannabidiol and its soft gel product (BD: May 26, 2021).

Today, the company said that the 540-patient, randomized, placebo-controlled, phase III trial would study the effect of the administration of 75mg and 150mg a day of its cannabidiol-tocopheryl phosphate mixture (TPM) versus placebo, across three different treatment groups.

Avecho said the primary endpoint was the reduction of insomnia severity after eight weeks of treatment, with two different scales.

The company said that secondary endpoints would examine specific aspects of sleep, including time to fall asleep, the time spent waking up after sleep was initiated and further endpoints related to other aspects of sleep and anxiety.

Avecho said that it would conduct an interim analysis after about 300 patients had been dosed to determine whether there was any effect present or if the trial should be terminated early.

The company said that the study had been designed to be relevant to the TGA, the US Food and Drug Administration and the European Medicines Agency “a key factor to support potential product registration in these leading global healthcare markets”.

Avecho chief executive officer Dr Paul Gavin said “everything we have learnt over the last 15 years of drug development has gone into this product and this study - and it’s a watershed moment for any biotechnology company and its investors to commence a phase III trial”.

“We are working with a trial design and host of respected professionals that will maximize the chance of success and eventual approval in multiple regions,” Dr Gavin said.

“The TGA has never assessed CBD in a submission package for pharmaceutical approval - similarly, no regulatory agency in the world has approved CBD for this indication,” Dr Gavin said. “This has motivated the Avecho team to work strategically and methodically to design a phase III trial that meets regulatory criteria in key markets.”

“It is hoped this will put us in a leading position for both regulatory approval and for negotiating significant commercial deals with leading international pharmaceutical companies,” Dr Gavin said.

Avecho was up 0.2 cents or 18.2 percent to 1.3 cents with 4.3 million shares traded.

## CHIMERIC THERAPEUTICS

Chimeric says it has dosed the third cohort in its phase I chlorotoxin chimeric antigen receptor T-cells (CLTX-Car-T-cells) for glioblastoma dose-escalation study.

In February, Chimeric said the second dose cohort at the Los Angeles' City of Hope, received intra-tumoral and intra-ventricular administration at  $88 \times 10^6$  CLTX-Car-T-cells, and it had "encouraging" activity signal with two of three evaluable patients achieving local stability of disease (BD: Feb 8, 2022).

Today, the company said that three patients in the third dose level received a total dose of  $240 \times 10^6$  CLTX-Car-T-cells through dual routes of intra-tumoral and intra-ventricular administration, and that the fourth and final planned dose level of  $440 \times 10^6$  CLTX-Car-T-cells would begin after the 28-day dose limiting toxicities period.

Chimeric was up half a cent or 6.4 percent to 8.3 cents.

## OSTEOPORE

Osteopore says it has "firm commitments" for a \$1 million placement at 15 cents a share and will buy four South Korean distributors for \$2,050,000 in cash and scrip.

Osteopore said that the placement price was a 25 percent discount to its closing price of 20 cents, and it would issue an attaching option for each share subscribed, exercisable at 22.5 cents within three years of issue.

The company said that it would use the funds to develop new products, advance clinical trials, expand its patents, strengthen its balance sheet and provide capacity for potential partnership and acquisitions.

Osteopore said that it had a non-binding term sheet with businesses from Lim Jae Hoon to buy the businesses owned by Lomic Korea Co, 3D Aesthetic Solutions Pte Ltd, 3D Healthcare Solutions Co and 3D Aesthetic Medical Equipment and Supplies Trading, for \$550,000 in cash, 2,400,000 performance rights, valued at \$1.2 million, which would convert to shares on milestone achievements and following completion, \$300,000 in three tranches, subject to milestone achievements.

The company said the businesses were medical distribution companies, primarily based in South Korea, Singapore, Vietnam and the Philippines and the acquisition would increase the distribution of its products.

Osteopore chair Mark Leong said "this proposed transaction marks our first acquisition... [and] creates synergies to our business and allows us to add exciting inorganic growth to complement our strong organic growth".

"We are excited by this transaction and will continually seek more opportunities to boost our trajectory," Mr Leong said.

Osteopore fell five cents or 25 percent to 15 cents.

## IMRICOR MEDICAL SYSTEMS

Imricor says it has a \$US1.5 million (\$A2.2 million) loan from the North Dakota Commerce Department's Innovation Technology Loan Fund for "financial flexibility".

Imricor said the Bank of North Dakota would structure and establish the loan at zero percent interest and no payments for the first three years of the loan, followed by two percent interest with monthly interest payments, for the next two years of the loan.

Imricor chair Steve Wedan said "the talent, business environment, and commitment to grow a [medical technology] sector in North Dakota all combine to make it an ideal location for Imricor".

Imricor fell half a cent or 1.3 percent to 37.5 cents.

## RACE ONCOLOGY

Race says it is donating \$US541,760 (\$A803,720) to the University of Texas MD Anderson Cancer Center to support an extramedullary acute myeloid leukaemia trial. Race said that the trial would use positron emission tomography (PET), computerized tomography (CT), and whole body magnetic resonance imaging to detect extramedullary leukaemia in acute myeloid leukemia patients.

The company said that the trial complemented its RAC-006 trial exploring the use of its Zantrene protein inhibitor in the treatment of extramedullary acute myeloid leukemia. Race was up one cent or 0.5 percent to \$2.05.

## ACTINOGEN MEDICAL

Actinogen says the US Food and Drug Administration has agreed to its 330-patient, six-month, phase IIb trial of Xanamem for early stages of Alzheimer's disease.

Actinogen said that the placebo-controlled, randomized phase IIb trial would evaluate the efficacy of 5mg or 10mg Xanamen versus placebo, daily, on attention and working memory scales including the clinical dementia rating scale, and the Cogstate computerized test battery.

The company said the trial would begin by July 2023, with results expected in 2024.

Actinogen chair Dr Geoff Brooke said the FDA approval of the phase IIb Alzheimer's trial was "a significant milestone for the company".

"This is a testament to the expertise of our management team, advisors and clinical investigators around the world," Dr Brooke said.

Actinogen was up 0.2 cents or 2.1 percent to 9.8 cents.

## THE CENTENARY INSTITUTE

Sydney's Centenary Institute says it has a \$995,867 grant from the New South Wales Government for its inhaled powder nasal vaccine.

The Institute said the grant, from the Covid-19 Vaccine Acceleration Research program would support work conducted with the University of Sydney, to develop a nasally inhaled, dry powder form of the Covid-19 vaccine to induce immunity in the airways and block transmission of severe-acute-respiratory-syndrome-coronavirus-2 (Sars-Cov-2).

The Centenary Institute said the vaccine would be inhaled to generate immunity in the nasal passages, as well as the airways and lungs, to provide protection from infection.

The Institute said that the effectiveness of the vaccine would be determined in pre-clinical models of Sars-Cov-2 infection as a "pathway to clinical trials in people".

The Centenary's tuberculosis research program head Prof Warwick Britton said there was an "urgent need for new vaccine strategies that block Covid-19 transmission".

"Although approved vaccines substantially reduce severe disease and hospitalization, there is little evidence they block viral transmission, especially for newly emerging variants," Prof Britton said.

"This is because current intra-muscular vaccines do not stimulate production of virus-neutralizing antibodies and T-cells in the nasal cavity and airways - sites where infection commences in the body," Prof Britton said.

"If successfully translated to the clinic, this vaccine strategy would be a transformative innovation in the fight against Sars-Cov-2, addressing needs not met by current vaccines," Prof Britton said. "It offers an approach to reduce Covid-19 related morbidity in vulnerable populations and also to limit viral transmission amongst the wider community, thereby reducing disruption to our economy and daily life," Prof Britton said.



## ANTEOTECH

Anteo has told the ASX that it did not have less than two quarters of funding available at September 30, 2022.

In a query, the ASX said that Anteo's Appendix 4C report for the three months to September 30, 2022, stated that it had an estimated two quarters of funding available but had rounded it up from about 1.959 quarters of funding, which was not permitted under ASX compliance rules.

The ASX asked Anteo if it had less than two quarters of funding available at September 30, 2022 and to answer the questions usually required in an Appendix 4C if a company had less than two quarters of funding available.

Anteo said that it did not have less than two quarters of funding at September 30, because "the calculation included in the Appendix 4C does not allow a company to take into consideration unusually high expenditure in the previous quarter, forecast of future cash flows and anticipated large inflows" including research and development tax incentives. Anteo said that it would "not have less than the current level of net operating cash flows for the time being" and that it had "higher than normal costs for clinical trials and other consulting" during the quarter.

The company said that it had taken further steps to raise cash and to fund its operations, including terminating a European clinical trial, receiving a \$3.2 million Federal Research and Development Tax Incentive, and completing a project "leading to high consulting fees".

Anteo said that it expected to achieve a higher level of net operating cash flows for the three months ending December 31, 2022.

Anteo was unchanged at 5.8 cents with 1.2 million shares traded.

## OVENTUS MEDICAL (IN ADMINISTRATION)

Oventus administrators Grant Thornton says that "the recapitalization strategy being undertaken by the company has been discontinued".

In June, Oventus said that it had appointed Grant Thornton's Michael McCann and Graham Killer as its voluntary administrators, and in September, the company said a group of new and existing investors hoped to recapitalize the business and remain listed on the ASX (BD: Jun 14, Sep 13, 2022).

Today, Grant Thornton said that Oventus would continue in voluntary administration, and it would consider opportunities for an alternative transaction.

Oventus last traded at two cents.

## CRYOSITE

Melbourne's Lindmark Investments Staff Superannuation Fund says it has increased its holding in Cryosite from 3,119,465 shares (6.39%) to 4,004,569 shares (8.20%).

Lindmark said it bought shares between October 25, and December 19, 2022, with the single largest purchase on December 19, of 650,000 shares for \$429,750 or 66.1 cents a share.

Lindmark said the registered holders were Mark Kerr and Linda Kerr.

Cryosite was unchanged at 67 cents.

## IMUGENE

Richard Mann and associates say they have ceased their substantial holding in Imugene due to dilution from the issue of shares on September 19, 2022.

In 2020, Richard Mann and associates said they had become substantial in Imugene with 249,496,995 shares or 5.66 percent of the company (BD Nov 4, 2020).

In September, Imugene said it had commitments to raise \$80 million in a placement at 20 cents a share (BD: Sep 13, 2022).

Imugene was unchanged at 15 cents with 10 million shares traded.

## PAINCHEK

Painchek says that Lisa Dadswell will replace Sally McDow as company secretary.

Painchek said that Ms Dadswell was an “experienced company secretary and corporate governance profession”.

The company said that Ms Dadswell held a Bachelor of Laws from Bournemouth University in Dorset, England.

Painchek was unchanged at 3.3 cents.