Biotech Daily

Thursday December 16, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: MESOBLAST UP 11%; CSL DOWN 8%, NOVA EYE 6%**

*** 2021 – THE YEAR IN REVIEW**

*** CSL RAISES $6.3b FOR VIFOR**

*** FEDERAL, VICTORIA MODERNA DEAL HITS IDT**

*** QBIOTICS LAUNCHES STELFONTA FOR DOG CANCER IN AUSTRALIA**

*** ORTHOCELL: CELGRO TENDON REPAIR 'SAFE, WARRANTS FURTHER STUDY'**

*** PROTEOMICS WINS $409k P-K TESTING CONTRACT**

*** TGA KNOCKS BACK PSILOCYBIN, MDMA DOWNGRADE; MIND MEDICINE**

*** BIONOMICS REQUESTS NASDAQ IPO TRADING HALT**

*** AVITA COMPLETES RECELL FOR VITILIGO ENROLMENT**

*** IMMUTEP: NORTHWAY TO MANUFACTURE IMP761**

*** MESOBLAST: FDA OTAT AGREE BACK PAIN ENDPOINTS**

*** PARADIGM: PPS 'IMPROVES HEART FUNCTION', IN RATS**

*** ALCIDION COMPLETES SILVERLINK ACQUISITION**

*** CRONOS COMPLETES CDA HEALTH MERGER**

*** CRONOS: HEADLEY 23.5%, BEN JANSEN 24%, DR JANSEN 10%, ROD COCKS 4%**

*** ZELIRA APPOINTS NUBU NEW ZEALAND MARIJUANA DISTRIBUTOR**

*** EMYRIA REQUESTS 'PARTNERSHIP' TRADING HALT**

*** PROF GRAHAM MITCHELL, BOB MOSES, WILL GOOLSBEE LEAVE ANTISENSE**

MARKET REPORT

The Australian stock market fell 0.43 percent on Thursday December 16, 2020, with the ASX200 down 31.4 points to 7,295.7 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, and nine traded unchanged.

Mesoblast was the best, up 14.5 cents or 10.9 percent to $1.475, with 8.9 million shares traded. Antisense climbed 5.6 percent; Actinogen, Prescient and Pro Medicus improved four percent or more; Cyclopharm, Imugene, Nanosonics and Universal Biosensors were up more than three percent; Starpharma rose 2.7 percent; Compumedics, Immutep, Opthea, Orthocell, Paradigm, Polynovo and Telix were up one percent or more; with Cochlear and Medical Developments up by less than one percent.

CSL led the falls, down $24.27 or 8.2 percent to its Vifor $273.00 placement price, with 4.1 million shares traded. Nova Eye lost 5.6 percent; Cynata and Osprey fell more than four percent; Avita was down 3.4 percent; Genetic Signatures, Impedimed, Optiscan and Patrys shed more than two percent; with LBT, Neuren and Resmed down more than one percent.

BIOTECH DAILY EDITORIAL – 2021: THE YEAR IN REVIEW

What a year!

The Biotech Daily Top 40 Index (BDI-40) closed 2021 up 24.6 percent for the year to November 30, the three Big Caps of Cochlear, CSL and Resmed (which are not included in the index) were up 17.5 percent and the benchmark ASX200 was up 11.3 percent.

Initial public offers (IPOs) rained like confetti at a pre or post Covid wedding.

Fourteen companies listed on the ASX at last count, VTI or VGL formerly known as Azure merged with Invictus - Dr Glenn Tong's company - listed on the National (formerly Newcastle, NSW) exchange and Zucero pulled an Australian biotech first by pulling its $30 million IPO because the US Food and Drug Administration approved its 61-patient, phase II cancer trial (see details below).

Anteris began the year with a $20 million funding package including a $16.5 million equity draw-down facility; Alterity (and previously Prana) executive chair Geoffrey Kempler stepped back to non-executive after nearly 16 gruelling years, handing the CEO role to chief medical officer Dr David Stamler; Pro Medicus quietly signed a $40 million deal with Utah's Intermountain Healthcare for its Visage 7 imaging platform; the FDA approved Orthcell's Celgro for dental procedures; and then we came back from Summer Holidays.

The first day back, Chimeric opened 60 percent above its $35 million IPO price (see below), Genetic Signatures won Conformité Européenne (CE) mark approval for its Easyscreen STI (sexually transmitted infection) test; Resmed, yet again, posted record quarter and first half-year revenue and profit and fell 0.7 percent on the good news, proving once again that the market is always right, apart from when it isn't – and that was biotech January in six sentences.

February

Ellume won a $303 million US production and supply deal for its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) home test; MGC raised $11.6 million to list on the London Stock Exchange at 1.475 British pence (2.6 cents) becoming the first marijuana company on the LSE; and roaring as high as 9.3 pennies, but currently worth tuppence. Cann Group called for an investigation for $3.5 million that was meant to be paid to two contractors, but was hacked from its system – biotech's first documented cybercrime.

After years of trials and FDA tribulations, Pharmaxis exported its first Bronchitol for cystic fibrosis to the US; Mesoblast added back pain to its list of trials not meeting its endpoints; Bard1 claimed 100 percent sensitivity and specificity for its ovarian cancer test and four days later added 95 percent sensitivity and 100 percent specificity for its breast cancer test – up 369.8 percent from 74.5 cents to $3.50 in two days. Well done, Dr Hinch.

Pro Medicus signed a $31 million deal with the University of California; Telix said the Czech approval of TLX591-CDx for prostate cancer imaging was its "first national approval"; CSL posted record first half-year revenue and profit; Cochlear's revenue slipped; Europe approved Starpharma's Viraleze SPL7013 anti-viral nasal spray, claimed to kill 99.9 percent of Sars-Cov-2 virus (along with bacterial vaginosis and STIs); the ASX delisted Invitrocue for not filing financial reports and Medigard for not paying its fees.

March
Mesoblast opened March with a mammoth $142 million capital raising, but said its net loss for the six months to December 31 was $64.7 million, with about $100 million in cash, providing a two year runway; the far leaner 4D Medical raised $40 million and noted a $28.9 million Federal Government grant for the Australian Lung Health Initiative; the FDA gave Nuheara's Iqbuds Pro for hearing loss the nod; cashed-up Auscann announced its marriage to Cannpal for dog hemp for osteoarthritis; Opthea took the first steps on the long road of two phase III trials of about 1,980 patients to convince the FDA to approve OPT-302 for wet age-related macular oedema; and Actinogen appointed Dr Steve Gourlay as CEO replacing Dr Bill Ketelbey, igniting something of a renaissance for Xanamem for Alzheimer's disease – and now several other indications, including depression. Given that the drug, UE2343, was invented for diabetes, one might add that to the list, too.

The public-unlisted Qbiotics won a $50 million investment from TDM for its Stelfonta for dog and human cancer and on the same day the Federal Government expanded its consciousness with $15 million for psychedelics including ketamine, magic mushroom psilocybin and MDMA or ecstasy. "Groovy, Greg," as they said in the 1960s.

After just 14 years, Respiri's Wheezo asthma monitor won FDA over-the-counter approval; Resapp's cough monitor won a TGA okay; Kazia signed a $380 million paxalisib deal with Simcere for brain cancer in Greater China; and we were gifted with yet another Industry Minister, the Hon Christian Porter, demoted from Attorney-General following a controversy he "vehemently denies". Six months later we inherited Angus Taylor.

April
CSL said that its very good idea of hyperimmune immunoglobulin for Covid-19 missed its endpoints, joining multiple companies trying remedies for the global pandemic; Universal Biosensors added the Tn antigen finger-prick test for most cancers to its recent foray into wine testing, showing that the new CEO John Sharman (previously of Medical Developments and Cyclopharm) had hit the ground running. China approved Uscom's BP+ for central blood pressure; and it emerged from the ether that weak marijuana with strong oxycodone doesn't do much for difficult-to-treat chronic back pain. The perfectly designed trial proved what it set out to prove, responsibility taken by the Medical Journal of Australia – a publication of the Australian Medical Association - which has a … "cautious" approach to marijuana.

Victoria announced $50 million for mRNA research and manufacturing; the FDA gave Impedimed's Sozo the tick for its heart failure index, as well as approving Next Science's Xperience no rinse anti-microbial; and Respiri put in a scrip bid for Adherium which had just raised $18 million, but Respiri's price fell and the offer became unattractive.

May
Covid-19 hit regulators in India, delaying the Dimerix trial of DMX-200 … for Covid-19; and finally, the patient and imaginative Michael Johnson, found a use for Rhinomed's nasal dilators, which didn't help cyclists breathe more oxygen and haven't taken off as anti-snoring devices. Michael's father was complaining of "brain tickling" with the PCR tests for Sars-Cov-2, so the quick-thinking CEO repurposed the dilators as test swabs. We believe that along with Ellume's tests, it was the first Australian success for The Virus; Victoria pledged $245 million for an Australian Institute of infectious Disease, incorporating the Burnet Institute in the popular Parkville biomedical precinct.

Staying with alliteration in ”p”, Painchek’s infant pain assessment software won EU and UK approvals, but the FDA questioned Paradigm on pentosan poly-sulfate for knee osteo-arthritis; the US regulator gave Micro-X a second approval for its Rover bedside mobile x-ray, showing the FDA is less fussed about devices and diagnostics than systemic drugs.

June
Emyria announced that a 2-month study of 474 patients showed that marijuana reduced opioid use among high opioid use patients by up to 34.2 percent ($p < 0.0001$), leaving us to ponder which trial we want to believe. Meanwhile Epsilon (formerly Hydroponics) announced a 140-patient trial of marijuana for young people with intellectual disabilities and severe behavioral problems. The results will be interesting, when published.

Returning to The Virus, Brandon Capital said it had $32.5 million with Uniseed and Dr Andrew ‘Twiggy’ Forrest’s Minderoo Foundation to trial Ena’s INNA-051 nasal spray for Sars-Cov-2 and other viruses. Brandon said the spray reduced Sars-Cov-2 replication by up to 96 percent in ferrets, so not quite the 99.9 percent claimed by Starpharma; Proteomics copped an ASX discussion and trading halt for claiming its Promarkerd test for diabetic kidney disease could save $51 billion a year and agreed to retract the claim. Ellume announced a deal with Delta Airlines for its Sars-Cov-2 test for travelers and followed with a deal with Alaska Airlines. Is there an Omicron Airlines?

Ellume’s test is available for $US50 ($A67), which compares to people visiting New Zealand paying $150 per person, and others returning from the UK with packets of multiple tests for free from the National Health Service.

July
Qbiotics won Australian approval of Stelfonta (tigilanol tiglate or EBC-46) for dog cancer; Cann Group recovered $1.2 million of the stolen $3.5 million and began proceedings in Hong Kong against Er Ya Trade; Polynovo ramped-up its US sales staff, expecting record revenue for its Novosorb burns treatment, later parting company with its CEO Paul Brennan over “management style” and is in the market for a hot-shot CEO; and July closed with the trumpeting of a $40 million Psychae Institute funded by an unnamed US company to study psychedelics (see Monday’s ‘Another Year In The Grass’).

All year, trials reached milestones, with data mining from previous studies showing that although the drug didn’t meet the set endpoints, other signals showed that it could be useful in a subset of patients or for indications or outcomes not mentioned at the start of the trial. We know the boards and shareholders want to salvage something, and sometimes there really might be some sort of signal, so design a new trial and test it. When one sets an “alpha” which becomes the “p” significance value, that’s the company’s call. It’s your trial. Design it properly. Going data-mining after the event, looks like … data-mining after the event.

August
The best news for August was Michael Johnson winning a New South Wales order for one million Rhinoswabs to prevent Sars-Cov-2 “brain tickling” followed by a Victoria order for the same number. The TGA approved Sydney’s Speedx Sars-Cov-2 lab test; Lifespot became Inhalerx for marijuana vaping; Creso went psychedelic; Incannex took a pot-shot at the Nasdaq and the Burnet Institute made a huge announcement – sans details – of its sale of 360 Biolabs to Bioagilytix Labs for “several hundred million dollars”.

The ASX became an activist regulator, pursuing a number of companies whose contacts, possibly stock brokers or investors, were able to find the phone number for the Australian Financial Review's Street Talk column and leak news of capital raisings ahead of the ASX being told. IDT was caught up in the enthusiasm, repeatedly asked questions about its mRNA deals with the Federal and Victoria governments, eventually announcing that it had produced the first mRNA vaccine drug product.

MGC claimed a $33 million marijuana and Cimetra deal with a Florida company registered the month before; and Creso blew out the candle on Red Light Holland.

In the August reporting period, 55 companies increased revenue for the year and 22 had revenue down. Sixteen years ago there was barely a score of companies with revenue.

September
Spring sprung good and confounding news. The BDI-40 was back in record territory, up 11.7 percent to $23.1 billion – along with the Big Caps, led by CSL, up 7.2 percent to a record $215.85 billion. But Imugene's "one-sided" p-value for a secondary endpoint in its 68-patient phase II trial of HER-Vaxx for gastric cancer sent Biotech Daily scurrying for the statistics text books, which thankfully were immediately to the right of the desk. A one-sided "p" (probability) value can be used when there is only one possible direction of outcome. If there is a possibility the drug might improve or worsen the outcome, it must be a two-sided "p" value. We agreed to disagree and Imugene said it was "awaiting the events needed for [overall survival] evaluation data". Stay tuned. Meanwhile, the company went on a gravity-defying run and is currently worth more than $3 billion, so we know that Paul Hopper and Leslie Chong are doing something right.

The Gina Rinehart and Thorney-Tiga-backed Little Green Pharma won a Western Australia psilocybin licence, perhaps explaining some of the mining magnate's comments about $2 a day workers' wages and the need for better ports for luxury super yachts.

In the US, an FDA "hold" on Queensland's Protagonist Rusfertide (PTG-300) for cancer sent its share price plummeting 62 percent, only to recover a month later, up 94 percent when the FDA removed the hold; and Immuron lost its bid for a Sars-Cov-2 vaccine company, with director Peter Anastasiou leaving the board, although his company Grandlodge remains a substantial shareholder.

October
On Friday October 1, the biotech industry was told that Bioshares founder David Blake had reached the terminal stage of his cancer and a "gofundme" page was established to raise $90,000 to make his end-of-life more comfortable, to pay for carers and other costs. By Monday, the sector was halfway to the target and exceeded it by the end of the week. It was uplifting to see the generosity of the industry for which David worked so tirelessly. His death on November 19 affected many of us and Biotech Daily says, again, thanks to everyone who contributed and cared. It really is why we are here.

The CSIRO claimed the Wolbachia pipientis bacteria sterilizes male Aedes aegypti mosquitoes preventing reproduction, potentially eradicating dengue, yellow fever and Zika that the mossie spreads. Hopefully they can use it on all mosquitos, for which David Attenborough has not been able to show any use in the cycle in the life, apart from providing a plot line for a movie starring his brother, Richard.

Lumos claimed its Febridx could save the US $2.5 billion a year by differentiating between bacterial and viral infections, and like Proteomics, following ASX input, decided to withdraw the claim; Ellume announced a recall of some of its Sars-Cov-2 tests following higher than expected false positive rates.

Annual general meeting season arrived and some companies discovered that punters don't always like the idea of directors and staff giving themselves options and performance rights before investors receive dividends, or the "performance" includes keeping a seat warm for one year. Some companies splash shares and options and see very little dissent, others are strongly opposed. This year saw some resistance and one or two directors resigning ahead of the meeting. Generally, a withdrawn resolution means the company has seen the proxy votes on the readout and dropped the director or the issue. Except for Alcidion. In what is believed to be a first, the company withdrew the 10 percent placement capacity vote. With a market cap above $300 million, the up-and-coming patient-management company hadn't realized it was too big for the 10 percent placement capacity. Not a bad reason for pulling a resolution.

November

As we entered the final straight, LBT won FDA approval for its APAS Independence "golden staph" MRSA module; Telix won a TGA green light for its Illucix kit for prostate cancer imaging; and the Australian regulator approved Next Science's Xperience surgical solution.

Creso appointed Western Australia Legalise Cannabis MLC Dr Brian Walker as a marijuana adviser but he thought about it over the weekend and resigned three days later, telling Biotech Daily that as a medical doctor and his position on a Parliamentary inquiry into hemp and cannabis it "didn't pass the pub test". Nor the bong test.

Then the Australian Federal Police knocked on doors, mainly in Sydney, asking questions about Everblu. Initially, Creso made no statement despite sharing its chair Adam Blumenthal with Everblu. Two trading halts later, the company said that ASIC wanted documents, Mr Blumenthal had stood aside and James Ellingford was interim chair.

There have been ASIC-AFP raids before, but they are very few and extremely far between.

The last that we recall was Dr Mervyn Jacobson's Genetic Technologies and that was a very long time ago.

What we haven't seen before is the Federal $20 billion Medical Research Future Fund doling out $8.8 million to Noxopharm – "one of the largest grants of its kind" – for Veyonda (also known as NOX66 or Idronoxil) and then withdrawing the grant.

November ended with Kazia launching its sixth trial for the year (five investigator-led); and three IPOs in three days (see details below) with Tissue Repair falling 41 percent and, surprisingly, Paul Hopper's Radiopharm down 35 percent despite being oversubscribed, while Artrya climbed 24 percent on its over-subscribed raising. We have our theories, but without seeing the details of those dumping shares will never know. Wouldn't it be good if we had some transparency around share transactions?

December
The year is not quite over, but 4D Medical had its first commercial scans in Melbourne, while Pacific Edge signed Melbourne's Northern Health to use its Cxbladder cancer test.

IDT announced it had produced mRNA vaccine material with the Monash Institute of Pharmaceutical Science; and a few days later the Victoria Government said that with the Federal Government it had enticed Moderna to establish its own mRNA facility somewhere in Melbourne.

Kazia claimed 30-patient, phase II data showing paxalisib benefit for glioblastoma; and Neuren jumped more than 100 percent on North America partner Acadia's news that its phase III trial showed significant benefit for trofinetide for Rett syndrome.

And just as we were hoping to relax at the end of the year, CSL put in a $17 billion bid for Switzerland's Vifor and Novartis pulled its $1.9 billion deal with Mesoblast, which must have been a rather stressful day at 55 Collins Street.

IPOs
Last year there were eight new listings. As mentioned above, this year was twice that number - if we include Zucero halting its IPO for good news.

Paul Hopper started the ball rolling, with **Chimeric** raising $35 million for its scorpion-venom, chimeric antigen receptor t-cells for cancer and opened 60 percent above the 20 cents IPO price.

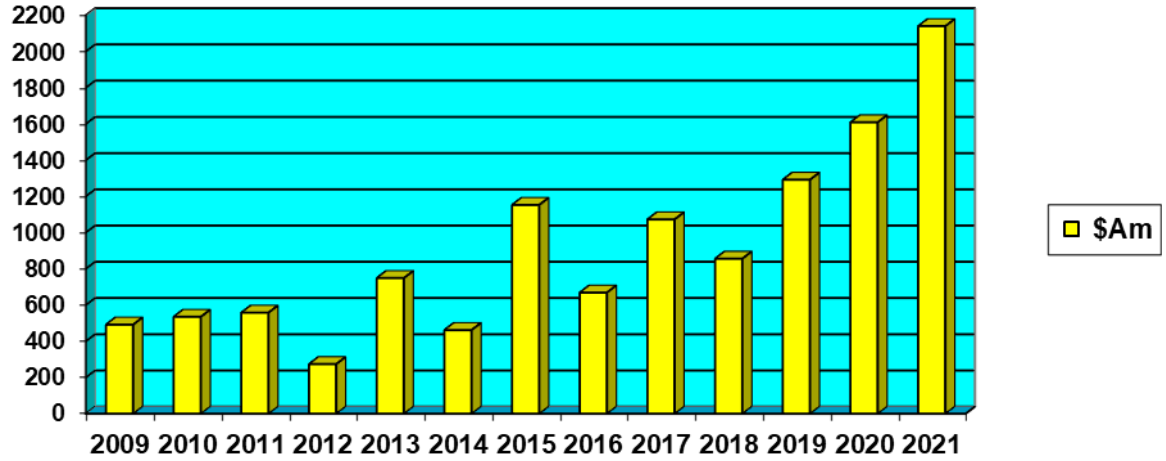
Paul MacLeman's **Island** had $44 million in bids for its $7.5 million IPO for mosquito-borne viruses; **Azure** raised $2.5 million of a hoped-for $3 million mostly from VGI chair Dr Vincent Lim Seng Peng and changed its name (again !) to VGI; and **Audeara** slipped five percent on its $7 million raise for its specialist headphones.

Trajan climbed 20 percent on a $90 million IPO for its complex diagnostics, quality control and analytics platforms; Planet Innovation's **Lumos** announced a $63 million IPO; **Argenica** raised $7 million for ARG-007 for stroke; **Zucero** announced the bad news that it had good news; **Clarity** claimed the mantle of largest IPO raising $92 million for copper radio-pharmaceuticals for diagnosis and treatment of cancer; and **BCal** was up 10 percent on its $10 million raise for cancer.

Auckland's **Pacific Edge** impressed with a 22.5 percent jump above its $1.31 ASX IPO price for bladder cancer tests; and Brandon Capital's Californian **EBR** stole Clarity's short-lived status, raising $110 million for its 'Wise' wireless pacemaker.

Tissue Repair fell 41 percent on its $22 million raise for wound healing; Paul Hopper's **Radiopharm** raised $65 in total for diagnostic and therapeutic radio-pharmaceuticals but fell 35 percent; **Artrya** raised $40 million for a clever use of software to detect dangerous arterial plaque and jumped 24 percent; and lastly, **Biome**, which we are not sure is actually biotech – despite the coveted ASX ticker of 'BIO'' - raised $8 million for over-the-counter, generally-regarded-as-safe (Gras) probiotics. At least it wasn't more marijuana grass.

Capital Raisings 2009 -2021



Yet another a terrible and disastrous year for biotechs. Not only is the BDI-40 just below its September 1 all-time record high, capital raisings are up at least 44 percent to $2,140 at the close of business today.

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

2020 AWARDS **(Judges: David Langsam, Marc Sinatra)**

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 Chair of the Year was easy. Imugene, Arovella (Suda), Chimeric and now Radiopharm - Paul Hopper is the chair about town.

We do have to address his critics. Paul finds interesting technologies at universities and institutes and wraps a company around them, which he then sells to an ASX-listed company or undertakes an initial public offer. Some people don’t like Mr Hopper retaining control of the company and he often has shares written into the prospectus. Earlier this year, both Paul and Imugene CEO Leslie Chong exercised options around 4.5 cents into shares worth about 45 cents.

Our main problem with this practice is that we didn’t think of it first and Paul hasn’t asked us to join any of his early-stage deals. It’s all above board, transparent and legal, even if it’s not usual. But we like unusual. It’s called innovation.

2021’s Chair of the Year goes to Paul Hopper.

CEO of the Year
The competition has been fierce.

Antisense’s Mark Diamond and Rhinomed’s Michael Johnson were front runners, until last week, when Team Neuren finally – after at least 16 short biotech years – announced North America partner Acadia’s phase III Rett trial of trofinetide, formerly known as NNZ2566 or Glypromate, met its endpoints with flying colors.

The runners-up include Atomo's John Kelly, Biotron's Dr Michelle Miller, Genetic Signatures' Dr John Melki, Kazia's Dr James Garner, Pro Medicus's Dr Sam Hupert, Proteomics' Dr Richard Lipscombe, Rhythm Biosciences Glenn Gilbert, Telix's Dr Behrenbruch, Universal Biosensors John Sharman and Volpara's Dr Ralph Highnam.

But the CEO of the Year can't be Team Neuren, so we have initiated a new award:

Team of the Year – which goes to former executive chair Dr Richard Treagus, current chief executive officer Jon Pilcher, long-suffering senior executive Larry Glass and everyone at Neuren who has worked on this, at times excruciatingly painful, journey.

The **CEO of the Year** goes to Alcidion's Kate Quirke for not only acquiring the UK's Extramed and signing at least three multi-million-dollar deals, apart from a Federal Government $23 million deal two weeks ago, but is in the midst of a $55 million capital raising, with most of it tucked away and the balance under-written as well.

Congratulations Kate Quirke.

Kamikaze of the Year

The competition in this space has also been fierce. Last year saw Covid-19-related claims that made the selection easier because most were claiming spurious tests or cures. There may be some low-hanging marijuana fruit, but dope is never going to cure coronavirus, herpes, heart failure or brain cancer. Those claims aren't really "biotech".

The Kamikaze award goes to companies that have flown themselves into the ground while aiming at other targets. Anteris – formerly Admedus, Allied Health and Biomd – has stripped itself back to developing interesting cow-based heart-valve replacements in a competitive subset of the sector. It has had a plethora of capital raises this year. The company trades around $8.00 but that follows two consolidations adding up to 1,000 shares for one, or equivalent to 0.8 cents before chief executive officer Wayne Paterson joined in 2014, when it was trading at 13 cents - a fall of 93.85 percent in seven years.

But there's worse: PYC is a contender appointing and losing US CEOs and publishing impenetrable announcements. We used to know what Phylogica was doing when then CEO Dr Stewart Washer explained that Phylomers were like the "bit" on a key without the handle, to block receptors, but the gibberish about RNA transports and pre-clinical results has us – and presumably retail investors - lost.

But there's worse. Why use plain language like "cancer drug" when Noxopharm can describe it as "a novel oncological pharmaceutical"? Not content with starting a trend of calling no change in disease "stable" it's now relayed as "success". Not in the FDA's eyes. And not in ours. Being in remission does not prove your drug cures cancer.

But there's worse. Ecofibre claimed marijuana success for gynaecological cancers in 31 women, by providing data on three in-vitro assays of endometriosis. Perhaps the company doesn't know that endometriosis is not cancer?

But there is worse. Announcing next to nothing all year, the former unproven Chinese medicine company, turned stem cell developer, turned marijuana company, returned to Chinese medicine, Stemcell United, matched Admedus for suspension extensions, recently saying it hoped to have acquisition news on December 24. Correct. Christmas Eve, when no one in their right mind is … er … in their right mind. On June 30, the company said it had a collaboration with Temasek Polytechnic to turn seaweed into "sea grape burger, green caviar sauce, sea grape ice-cream and low GI seaweed noodles".

Or perhaps Esense? Marijuana flavored beer? Marijuana for coronavirus? Seriously? The company voted to delist from the ASX and try its luck in Canada "where it considers [it] will have greater access to capital, and shareholders will have the benefit of increased liquidity". It left the ASX 91 percent below its 20 cents IPO price at 1.8 cents.

Given we already had Cann Group, it was curious that Queensland Bauxite chose a very similar name for its marijuana foray, Cann Global. It has fallen 75 percent from 0.8 cents a year ago, to 0.2 cents last night. The company promised a trial of marijuana to slow multiple sclerosis, imported cannabidiol from Canada and launched cosmetics.

The Kamikaze Award for 2021 is a joint award to Esense and Cann Global which has done not a lot all year - apart from give former chair Pnina Feldman 70,000,000 shares.

Accounts department

Biotech Daily will have a small increase in the base rate for subscriptions in the New Year. We have again added staff to cope with the increased workload and our writers demand to be paid. Even the IT guys (no women, yet) want to be paid.

Summer holiday publishing schedule

Biotech Daily will shut down for the long, hot, Australian Summer tomorrow, December 17 and be back on deck refreshed and recharged on Monday January 17, 2022.

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, Marc Sinatra and Michael Ibbott for invaluable wisdom, insights and cautions throughout the year.

Biotech Daily thanks its staff: Tim Boreham, guest columnist Peter Olszewski, Rowena Sidhu, Noah Nicholas, Alice Lynch 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, a Merry Christmas, Summer Solstice and Hogmanay/New Year and see you all in 2022.

David Langsam, Editor

CSL

CSL says it has raised $6.3 billion at $273.00 a share for the acquisition of the St Gallon, Switzerland-based Vifor Pharma and hopes to raise up to $750 million in a share plan.
CSL said the price was an 8.2 percent discount to its previous closing price of $297.27.
On Tuesday, the company said it would acquire Vifor for $US12.3 billion ($A17.2 billion) for its renal disease and iron deficiency expertise (BD: Dec 14, 2021).
CSL said it would offer $US179.25 per share for Vifor, a 40 percent premium to the "unaffected 60 trading day volume weighted average price" to December 1, 2021.
The company said that the acquisition would be funded by a $6.3 billion fully underwritten placement, $8.4 billion new debt and existing cash and a non-underwritten share plan at $273.00 a share for up to $750 million.
Today, the company said that under the share plan, investors could apply for up to $30,000 of new shares at a two percent discount to the five-day volume weighted average price (VWAP) of CSL shares to the closing date of the plan, currently scheduled for February 7, 2022.
CSL said details of the plan were expected on December 21, 2021.
CSL fell $24.27 or 8.2 percent to $273.00 with 4.1 million shares traded.

IDT AUSTRALIA

IDT says that its submission to the Federal Government to establish an onshore mRNA manufacturing capability "has not been selected to progress to the next stage".
In November, IDT said that with Monash University's Institute of Pharmaceutical Sciences it had manufactured severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) mRNA vaccine and the drug product "met all specifications" and was progressing through the release process to be supplied to MIPS for their clinical trial (BD: Nov 30, 2021).
Today, the company said that on December 14, the Federal Government announced with the Victoria Government that a new manufacturing facility will be built in Victoria with Moderna to produce respiratory mRNA vaccines in the onshore mRNA approach to market (ATM) process (BD: Dec 14, 2021).
IDT said it was "awaiting a response from the [Federal] Government on its submission for part of the $800 million [Modern Manufacturing Initiative] Collaboration Stream Grant.
IDT chief executive officer Dr David Sparling told Biotech Daily that the amount for which the company had applied had not been disclosed and IDT did not have continuing funding for mRNA development work "at this time".
In a media release, IDT said it was "liaising directly with the [Federal] and Victorian Governments to better understand their approach to supporting Australia's mRNA translation and manufacturing ecosystem more generally, along with the Australian Government's position on IDT's MMI Collaboration Stream Grant application".
The company said that the Federal Government had confirmed that its MMI Collaboration Stream Grant Application remained "live and … unaffected" by the ATM decision.
"Whilst we are disappointed in the outcome of the ATM process, IDT has developed and progressed several alternative strategic options," Dr Sparling said.
"The company has successfully delivered on the Monash Institute of Pharmaceutical Sciences Covid-19 mRNA receptor binding domain vaccine candidate project, being Australia's first locally manufactured cGMP mRNA finished product and clearly showcases IDT's manufacturing capabilities in this regard," Dr Sparling said.
"IDT is now sterile licenced and is maintaining its sterile facilities in a state of readiness to accept Covid-19 vaccine content at the Government's discretion," Dr Sparling said.
IDT fell 19 cents or 39.6 percent to 29 cents with 12.4 million shares traded.

QBIOTICS GROUP

Qbiotics says it has begun commercial sales in Australia of its intra-tumoral Stelfonta for dog non-metastatic mast cell tumors in Australia.
In July, the Australian Pesticides and Veterinary Medicines Authority approved Stelfonta, also known as tigilanol tiglate and EBC-46, for the treatment of non-metastatic mast cell tumors in dogs (BD: Jul 8, 2021).
Qbiotics managing-director Dr Victoria Gordon said that “after many years of research and development, we are delighted to see the commercial launch of Stelfonta in Australia”.
The company said that with marketing and distribution partner, the Carros, France-based Virbac SA, it would launch Stelfonta to Australian veterinarians.
Qbiotics said that Stelfonta was on sale in a number of other jurisdictions and had been approved by the US Food and Drug Administration, the European Medicines Agency, the UK Veterinary Medicines Directorate and Switzerland’s Swissmedic.
The company said that a 22-patient, phase I/IIa tigilanol tiglate dose escalation safety trial had been completed with a broad range of refractory solid tumors (BD: Dec 10, 2019).
Qbiotics said trials were in progress for head and neck cancer and melanoma, with preparation for trials in soft tissue sarcoma underway.
Qbiotics is a public unlisted company.

ORTHOCELL

Orthocell says the publication of results on 17 of 18 patients show that Celgro has the potential to promote tendon repair.
Orthocell said the study, co-authored by chief scientific officer Prof Minghao Zheng and titled, ‘A bio-inductive collagen scaffold that supports human primary tendon-derived cell growth for rotator cuff repair’ was published in the Journal of Orthopeadic Translation and was available at: https://bit.ly/3dTPc2X.
The company said one patient was withdrawn from the study at three months due to wound infection unrelated to the Celgro bioactive collagen scaffold.
The abstract said that magnetic resonance imaging assessment at 12 months showed complete healing in 11 of the 17 patients (64.8%), three patients experienced partial thickness re-tears (17.6%) and three had full thickness re-tears (17.6%).
The article concluded that bioactive collagen scaffold was composed of type-I collagen that was “free of immunogenic proteins and supported tendon-derived cell growth under mechanical loading in-vitro”.
The pilot study showed that Celgro was “safe and feasible to use [bioactive collagen scaffold for rotator cuff] argumentation and further controlled prospective studies are required to demonstrate its efficacy”.
Orthocell was up half a cent or one percent to 52 cents.

PROTEOMICS INTERNATIONAL

Proteomics says it has been awarded a $409,000 pharmaco-kinetic testing contract with the Nedlands, Western Australia based Linear Clinical Research.
Proteomics said the study would test an undisclosed novel drug for degenerative and inflammatory diseases on behalf of the Australian arm of the Beijing-based pharmaceutical company Sironax Ltd.
The company said the agreement supported its integrated business model and aim to exploit its specialized biomarker discovery and analytical services capabilities.
Proteomics was unchanged at $1.125.

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

The Therapeutic Goods Administration has refused requests to downgrade 'magic mushroom' psilocybin and MDMA or ecstasy from schedule 9 of the Poisons Standard.

The TGA refused separate applications for psilocybin and MDMA in a document, titled 'Notice of final decision to not amend the current Poisons Standard - Psilocybin and MDMA' which has been published on its website, at: https://bit.ly/3sagDxJ.

The TGA referred to MDMA as 'N, alpha-dimethyl-3,4-methylene-dioxy-phenylethyl-amine' which is different to the Biotech Daily use of '3,4-methylene-dioxy-meth-amphetamine' and the regulator told Biotech Daily that the two chemical compositions were equivalent "and interchangeably refer to the substance commonly known as MDMA".

The TGA said that 'N, α-dimethyl-3,4-(methylenedioxy) phenylethylamine' was the name used in the Poisons Standard and was placed into the Standard by the National Drugs and Poisons Schedule Committee in February 2004 and was the name used by the World Health Organization in the List of Psychotropic Substances under International Control.

Yesterday, the TGA published summary and detailed responses to as unnamed applicant or applicants who "proposed to down-schedule psilocybin from Schedule 9 (prohibited substance) to Schedule 8 (controlled substance) for use in a medically controlled environment".

The TGA said that as a Schedule 9 substance, its use is limited to medical and scientific research, subject to regulatory controls.

"The request for down-scheduling to Schedule 8 was intended to increase patient access through additional pathways such as the special access scheme," the TGA said.

"Pursuant to regulation 42ZCZR of the regulations, a delegate of the secretary has made a final decision to confirm the interim decision and not amend the current Poisons Standard in relation to psilocybin," the TGA said.

Similar terminology was used in relation to MDMA.

"I have reached this conclusion having weighed the risks to patients and public health from any increased access against the currently limited evidence of benefit," the TGA delegate said.

"Specifically: the benefit is very limited because psilocybin studies indicate only potential therapeutic value in circumstances where the treatment was provided to subjects within the setting of a clinical trial; the therapeutic value is not established, which corresponds to the scheduling factors for schedule 9," the TGA delegate said.

"In relation to the risks, I am satisfied that psilocybin poses a high danger for both acute and long-term effects if abused or misused by way of access outside of strictly controlled medical and scientific research settings," the delegate said. "This could arise due to diversion for illicit purposes across the supply chain if there is down-scheduling from schedule 9."

The delegate gave a similar response to MDMA saying that "the controls surrounding access under schedule 9 remain appropriate … [having weighed the risks to patients and public health from any increased access, against the currently limited evidence of benefit".

Mind Medicine Australia chair Peter Hunt said his group was "bitterly disappointed by the TGA's decision because, in our view, the medical use of both psilocybin and MDMA within controlled medical environments by trained professionals should come squarely within schedule 8 of the Poisons Standard".

Mr Hunt said the view was "echoed by the many researchers and medical practitioners" and said that the decision "leaves little hope" for people with treatment resistant depression and treatment resistant post-traumatic stress disorder.

"We also respectfully believe that there are many errors and inconsistencies in the delegate's published reasons for refusing these applications," Mr Hunt said.

BIONOMICS

Bionomics has requested a trading halt pending an announcement “regarding…its proposed US initial public offering … on [the] Nasdaq”.
Trading will resume on December 20, 2021, or on an earlier announcement.
Bionomics last traded at 11.5 cents.

AVITA MEDICAL

Avita says it has completed the enrolment for its blinded, randomized, pivotal trial of the Recell System for re-pigmentation of stable vitiligo.
In 2020, Avita said it had enrolled the first of up-to 84 patients in the multi-centre, pivotal trial of Recell for vitiligo to evaluate the safety and effectiveness of its spray-on skin at 24 weeks to re-pigment skin (BD: Sep 14, 2020).
Today, Avita chief executive officer Dr Mike Perry said recruitment of the last patient in the trial was “a significant milestone and lays the groundwork for the regulatory approval and commercialization of the Recell System in 2023 for use in patients with stable vitiligo”.
Avita fell 12 cents or 3.4 percent to $3.38 with 463,963 shares traded.

IMMUTEP

Immutep says it has contracted the Vilnius, Lithuania-based Northway Biotech to manufacture IMP761 for its clinical trials.
Immutep said IMP761 was a pre-clinical candidate for autoimmune diseases and an immune-suppressive agonist antibody to LAG-3.
The company said IMP761 had been tested in a T-helper type-1 (Th1)-driven autoimmune disease, oligoarticular juvenile idiopathic arthritis, as a proof of concept which was published in the Paediatric Journal in October 2021.
Immutep said that Northway had begun developing a good manufacturing practice-compliant process and would manufacture IMP761 in large-scale bioreactors.
Immutep said the agreement included the potential for further process scale-up and commercial supply.
Immutep was up half a cent or 1.1 percent to 47.5 cents with two million shares traded.

MESOBLAST

Mesoblast says the US Food and Drug Administration has approved its primary endpoint of pain reduction at 12 months for its next chronic back pain trial.
In February, Mesoblast said rexlemestrocel-L provided pain relief and opioid reduction for lower back pain, but “did not reach statistical significance” (BD: Feb 11, 2021).
Today, Mesoblast said the FDA Office of Tissues and Advanced Therapies agreed with the primary endpoint of the trial with functional improvement and reduction in opioid use as secondary endpoints.
Mesoblast said if the trial was successful and led to EU approval, it would be eligible to receive payments up to $US112.5 million ($A157.2 million) before the EU product launch, from its EU and Latin American partner Grünenthal “if certain clinical and regulatory milestones are satisfied and reimbursement targets are achieved”.
The company said that cumulative milestone payments could reach $US1 billion depending on the final outcome of phase III studies and patient adoption and it would receive tiered double-digit royalties on product sales.
Mesoblast recovered 14.5 cents or 10.9 percent to $1.475 with 8.9 million shares traded.

PARADIGM BIOPHARMA

Paradigm says its pentosan polysulfate sodium shows potential improvement in cardiovascular function and tissue preservation, in rats.
Paradigm said the proof-of-concept study conducted in 12 rats in two groups, with the first group, ZSF1 obese rats receiving 9.3mg/kg PPS once weekly, equivalent to 1.5mg/kg in humans, and the second group of ZSF1 obese rats received vehicle.
The company said the diastolic heart function was improved in PPS-treated rats ($p < 0.1$) compared to vehicle-treated rats.
Paradigm said it intended to conduct another pre-clinical trial to confirm the results and a market analysis to "best understand the patient population for clinical translation".
Paradigm was up two cents or 1.1 percent to $1.91 with 862,810 shares traded.

ALCIDION

Alcidion says it has completed the acquisition of the Newcastle, England-based Silverlink Software for its patient administration system.
Last week, Alcidion said it hoped to raise $55 million at 25 cents a share to acquire Silverlink (BD: Dec 7, 20210.
The company said that Silverlink was "one of the largest and few remaining specialist patient administration system providers servicing the UK [National Health System]" and its Patient Case System was recognized as flexible and cost-effective to full electronic patient records without a single supplier locked-in.
Today, Alcidion said that the acquisition provided Alcidion with a core patient administration systems capability, expanding its product range.
Alcidion was up one cent or 4.1 percent to 25.5 cents with 6.7 million shares traded.

CRONOS AUSTRALIA

Cronos says it has completed its CDA Health Pty Ltd merger, with all resolutions to its annual general meeting passed by more than 99.7 percent of votes.
In September, Cronos said it would acquire Varsity Lakes, Gold Coast, Queensland-based CDA (formerly Cannabis Doctors Australia), for up to 439,784,282 shares subject to conditions including shareholder approvals (BD: Sep 14, 2021).
The company said the merger agreement provided for cash payments of up to $5 million in cash for CDA shares subject to certain conditions.
Today, Cronos said it issued 403,552,399 shares and paid $5 million in cash to the shareholders of CDA Health for 100 percent of CDA Health, which was now a wholly owned subsidiary with former shareholders collectively owning 73.6 percent of Cronos.
The company said directors Daniel Abrahams, Jason Adler, Anna Burke and Michael Gorenstein had resigned with Guy Headley, Dr Benjamin Jansen, Kurt Schmidt and Dr Marcia Walker appointed to the board.
Cronos said it issued a total of 15,176,065 ordinary shares to Cronos Global Holdings Inc upon the "conversion of the outstanding loan and certain intellectual property licence royalties owed to Cronos Group by a subsidiary of Cronos Australia, which had a face value of $2,094,297 and which has now been fully repaid".
Cronos said a further 1,086,957 ordinary shares were issued to Cornwalls Capital Australia Pty Ltd in part payment of corporate advisory fees.
The company said a total of 548,565,421 Cronos Australia shares were on issue with 407,052,727 shares subject to voluntary escrow for 12 months to December 16, 2022.
Cronos was up half a cent or 2.4 percent to 21 cents.

CRONOS AUSTRALIA

Following the Cronos and CDA merger, several substantial shareholding notices have been filed.
Guy Headley and Benjamin Jansen said they became substantial with 128,952,151 shares (23.51%) and 129,890,570 shares (23.68%) respectively.
CDA Health co-founder, Dr Matua Jansen said he became a substantial share-holder in Cronos with 55,413,425 shares or 10.10 percent.
Cronos managing-director Rod Cocks and Newsouthern Investment Holdings 1 said they ceased their substantial shareholding following the merger.
Biotech Daily calculates that Mr Cocks and Newsouthern hold 3.6 percent of the company.

ZELIRA THERAPEUTICS

Zelira says it has a five-year marijuana distribution deal with Auckland's Nubu Pharmaceuticals, for New Zealand.
Zelira said that the distribution agreement expanded the availability of Zenivol for insomnia and Hope marijuana products.
The company said that Nubu would apply for New Zealand Ministry of Health registration for both products.
Zelira said that Nubu was required to purchase at least $2.6 million in minimum quantities of Zenivol and Hope totalling over the five years, with $178,000 in the first year.
Zelira was up 0.1 cents or three percent to 3.4 cents.

EMYRIA

Emyria has requested a trading halt pending "an announcement in regard to a potential technology partnership for its MDMA-assisted therapy trial program".
Trading will resume on December 20, 2021, or on an earlier announcement.
Emyria last traded at 37 cents

ANTISENSE THERAPEUTICS

In Final Director Interest Notices, long-serving directors Prof Graham Mitchell, Bob Moses and William Goolsbee said they had left Antisense on December 15, 2021.
In July, Antisense said Dr Charmaine Gittleson would replace Bob Moses as the chair with Mr Moses to retire at the annual general meeting (BD: Jul 28, 2021).
Mr Moses and Prof Mitchell were appointed directors in 2001 and Mr Goolsbee in 2015.
Antisense was up one cent or 5.6 percent to 19 cents with 1.15 million shares traded.