



Biotech Daily

Thursday December 17, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ANTISENSE UP 36%; LBT DOWN 8%**
- * **BIOTECH DAILY EDITORIAL: 2020 - THE YEAR IN REVIEW**
- * **PRO MEDICUS, MEDSTAR \$18m, 5-YEAR DEAL FOR VISAGE 7**
- * **MICRO-X, ADF \$1.3m DEAL FOR ROVER MOBILE X-RAY**
- * **RACE RECEIVES \$387k FEDERAL R&D TAX INCENTIVE**
- * **IMUGENE RECRUITS 1st PD1-VAXX LUNG CANCER COHORT**
- * **ORTHOCELL CELGRO PASSES TGA CONFORMITY ASSESSMENT**
- * **MEDADVISOR \$4m SHORTFALL, TOTAL \$42.2m; \$6.5m NEW CONTRACTS**
- * **THC RAISES \$2.75m FOR MEDIMAR AND MANUFACTURING**
- * **NEUROTECH \$366k PLACEMENT, 38m EMPLOYEE, MANAGER OPTIONS**
- * **RHYTHM US PATENT FOR COLOSTAT BIOMARKERS**
- * **IMMUTEP EXPANDS IMP321 MANUFACTURING CAPABILITY**
- * **FIL (FIDELITY) INCREASES, DILUTED TO 9% IN TELIX**
- * **UNIQUEST BELOW 5% IN EMVISION**
- * **ACRUX REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **VISIONEERING TO RELEASE 6.6m VOLUNTARY ESCROW SHARES**
- * **ANTERIS LOSES STAR BRIGHT DIRECTOR DR YANHENG WU**
- * **EMVISION APPOINTS PROF STUART CROZIER CSO**
- * **PRESCIENT APPOINTS PROF HENRY MILES PRINCE SCIENTIFIC ADVISOR**

MARKET REPORT

The Australian stock market was up 1.16 percent on Thursday December 17, 2020, with the ASX200 up 77.5 points to 6,756.7 points. Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

Antisense was the best on no news for the second day in a row, up four cents or 36.4 percent to 15 cents, with 37.0 million shares traded. Prescient climbed 6.45 percent; Telix improved 4.2 percent; Alterity, Polynovo, Pro Medicus and Starpharma were up more than three percent; Nanosonics, Orthocell, Pharmaxis, Proteomics and Universal Biosensors rose more than two percent; Avita, Cochlear, Compumedics and Nova were up more than one percent; with Clinuvel, CSL, Cynata, Medical Developments and Resmed up by less than one percent.

LBT led the falls, down one cent or eight percent to 11.5 cents, with 1.3 million shares traded. Cyclopharm and Impedimed lost more than seven percent; Resonance retreated 6.8 percent; Dimerix fell 4.65 percent; Genetic Signatures was down 3.5 percent; Immutep and Next Science shed more than two percent; Kazia and Opthea were down one percent or more; with Volpara down 0.8 percent.

[BIOTECH DAILY EDITORIAL: 2020 - THE YEAR IN REVIEW](#)

The year started well with the Biotech Daily Top 40 Index (BDI-40) closing 2019 up 118 percent

Reva Medical failed to commercialize its bioresorbable stents and, like its US compatriot Airxpanders, departed the ASX boards, later followed by GI Dynamics.

At the end of a quiet January, the sector was a little excited by Resmed paying \$60 million to resolve US “kickback” allegations, the TGA cancelled Neurotech’s Mente Autism product sending the company onto the grassy knoll of medical marijuana and the BDI-40 hit an all-time high with a collective market capitalization of \$16,788 million – up 13.1 percent on January and 125.1 percent on the previous year.

The Virus

All was good with the world, but bubbling away in Wuhan, China, and being transmitted across the globe by travellers of all descriptions was a small microbe then known as 2019-nCov, later to change its name and take centre stage as severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) before shortening the moniker to just Covid-19.

From hoax, to bad ‘flu, the world slowly woke up to the fact that it was a virulent little bug with spikes perfectly designed for graphic representations and much-loved by cartoonists. David Rowe in the Australian Financial Review uses it with aplomb.

The Peter Doherty Institute was the first Australian organization to say it had something to do with what would become a global pandemic, growing the virus in a laboratory. But then the Coronavirus Bandwagon began to roll. By mid-February, Uscom was answering ASX questions about cardiac monitor sales in China and in March, Cellmid caught the ASX’s attention for claims about importing Chinese tests for The Virus, while TBG Diagnostics (formerly Progen) said a subsidiary had been approved by China as a coronavirus testing laboratory. The company jumped 92.9 percent to 27 cents in mid-March before requesting a trading halt, and remains suspended at 27 cents, despite CE mark and FDA approvals.

This was when media reports became horrifyingly confused about the difference for a test for the Sars-Cov-2 virus living up one’s nose (antigen test) and a person’s immune response to the virus (Covid-19 antibody test). Most helpfully, a large number of would-be diagnostic companies confused the two, saying that investors just wanted to know whether they had a test for ... you know ... THAT bug.

Pity the poor ASX advisers (the ASX-company contact) trying to sift the chaff from the grain. Luckily, the ASX had a re-organization two years ago with advisers covering industries rather than geographies. Nevertheless, some biotechs have become very adept at saying things that Normie Rowe wouldn’t find in a bible.

In March, the Doherty Institute joined global Covid-19 trials looking for a cure and as global markets fell amid concerns that the hoax wasn’t, Cochlear boldly went where no biotech had gone before: a \$1.1 billion, heavily discounted placement and rights issue to make sure it survived. Meanwhile Resmed turned its technology from pumped air face masks to ventilators to be well and prosper ... and the announcements took off.

The Plague

By April Fool's Day, all indices had fallen significantly and Noxopharm became the first Australian company to make a link between its Idronoxil (Veyonda or NOX66) and suppression of "the cytokine storm" immune reaction to Covid-19. Noxopharm was followed by Cynata (which had shown this in mice in 2018) and Mesoblast, with Mesoblast the only one to date to have (limited) trial data to back the claim – and awaiting definitive data, any time soon.

The number of companies claiming to have something useful for The Virus multiplied ... like a virus ... with diagnostics, drugs for prevention, treatment, suppression or something, being touted by a large number of the usual suspects. Rubbing marijuana on coronavirus became a near daily sport with some understanding that once the punters had come on board and pushed the price from 5.0 cents to north of 20 cents it was a good time for a 15 percent discounted placement and share plan.

It was difficult for the novices to discern which were the serious players and which were the spruikers and Biotech Daily called on the latter to just stop. But we weren't helped by the Doherty and WEHI lending their names to "testing" compounds on a pay-to-play basis.

Oncosil finally won long-awaited Conformité Européenne (CE) mark approval, as well as US and EU breakthrough device designation, for its radiation treatment for pancreatic cancer (co-invented by director Dr Roger Aston), followed by Malaysia, New Zealand and Switzerland approvals and applications to the FDA, but nothing seemed to help the share price, so Oncosil resolved the problem by "terminating" the chief executive officer who did all the work, Daniel Kenny. When in doubt, sack a CEO.

Atomo listed on the ASX having raised \$30 million and announced it had orders for millions of rapid Covid-19 tests, based on its rapid HIV test.

Benitec bit the dust, or in the terms of last year's press release migrated to the Nasdaq to reduce costs and "provide access to a broader range of US investors" following multiple trial successes showing its drugs didn't work for HIV, hepatitis C and oculo-pharyngeal muscular dystrophy. At one time a promising drug developer with a market capitalization of \$162 million (Mar 30, 2014), Benitec left Australia worth \$8 million, with the better valuations of the Nasdaq putting it at \$16 million, roughly its 15-year ASX average. Bard1 acquired Sienna, which didn't make a lot of sense other than reducing two struggling companies down to one, and we await the next great leap forward.

Mesoblast showed that its stem cells –the ones acquired from Osiris for graft-versus-host disease - showed efficacy in a small trial of ventilator-dependent Covid-19 patients and won FDA approval for a 300-patient, phase III trial. Depending on their technologies, companies began either warning that trials would be delayed or that revenue was up.

Following the February and March falls, biotech bounced back in April recovering most of its losses and companies continued making announcements about actual work other than the Covid-19 bandwagon. This was greatly assisted by the ASX clampdown on anything Covid-related. It caused concern for a number of serious companies who were collateral damage to the spruikers. We were grateful to Recce for showing that R-327 reduced gonorrhoeae in mice.

CSL took a 15-year, \$1.2 billion loan at rates ranging from 2.38 percent to 2.83 percent, Pharmaust claimed “success” in its trial of Elanco’s sheep worm treatment Monapantel with one dog of seven having a tumor reduced and later claimed the drug had potential for Covid-19. Mesoblast raised \$139 million, Cyclopharm sold Technegas to Russia and Cynata said it was “pleased” with \$11 million in bids for a \$2 million share plan.

By June 1, we could see that biotech was flavor of the year and said the BDI-40 was “fully recovered” at a collective value of \$16,106 million, the second best after the February all-time high. The public unlisted Clarity had made several promising announcements about its copper-based diagnostic and therapeutic radiation technology for cancer – a similar aim to the ASX-listed Telix – and won FDA rare disease designation for neuroblastoma.

In less good news, former Sirtex chief executive officer Gilman Wong was lucky to score a three-year good behavior bond following a conviction for insider trading. The maximum penalty was 10 years of Her Majesty’s porridge.

Opthea disappointed with OPT-302’s non-significant success for diabetic macular oedema, which contrasted to last year’s clearly significant success for wet aged-related macular degeneration. The share price jumped from 87 cents to \$2.25 last year, climbing to \$3.74 before the bad news, and currently trading above \$2 means the market believes in the company.

The Victoria Government unveiled a \$250 million Business Growth Fund for small to medium enterprises, the day after MTP Connect claimed the sector had been hit hard by the coronavirus shut down. But it was a curate’s egg, as they say. The impact was primarily on donations to research institutes and with some clinical trials delayed. But there was also the upside of a much greater focus on the sector. Cynata surprised by turning a small phase II trial of Cymerus stem cells for arthritis into a 440-patient, phase III trial at the University of Sydney, and Kazia said its 30-patient phase II trial of paxalisib for glioblastoma showed it was superior to the FDA-approved temozolomide. Ellex prepared to sell off its major revenue earning laser and ultrasound business, for a tidy \$100 million, leaving it with a clear focus on glaucoma treatment.

More and more companies – including ones from which we had never previously heard - claimed “potent activity” for Sars-Cov-2 or Covid-19 or The Virus, and uniformly “in-vitro” – that is, in a Petri dish in a laboratory. From interesting early studies, they became a daily annoyance (see below). We were grateful to Starpharma showing that multiple DEP-cancer-drug-combinations showed efficacy in mice.

June 30 heralded the 14-year data that the BDI-40 was up 450 percent, compared to the bottom bumping ASX200 up 16 percent in 14 years. The collective market capitalization for the three Big Caps of Cochlear, CSL and Resmed was up 963 percent.

Sydney clinical research organization Greenlight Clinical said that despite the coronavirus pandemic “Australia is already showing signs of recovery from the perspective of studies on clinical therapeutics” and while 360 clinical trials were expected to begin in the six months to June 30, 2020, 18.2 percent below the previous year, Australia had returned to the monthly count of study initiations in January, before The Virus.

Distracting from coronavirus claims, Micro-X won FDA approval for its 95kg mobile x-ray system for military medical facilities for trauma imaging, while the unlisted Queensland Qbiotics dosed its first Australian patient in a phase I/II trial of tigilanol tiglate for head and neck cancer, and Impedimed finally launched its Sozo diagnostic for heart failure.

New Zealand's Aroa raised \$30 million to list on the ASX to commercialize its Endoform sheep gut wound treatment and opened up 86.7 percent at \$1.40. On the same day Immuron raised \$28 million and Emvision \$9 million.

The Vaccine

Biotech Daily finally spat the dummy and called the Doherty Institute to find out what all this nonsense was about it "selecting" every molecule under the Sun as a "tier 1" candidate for curing coronavirus. The Doherty, CSIRO and the University of Melbourne produced something of a distancing from the claims made by a plethora (we choose the word, wisely) of companies that their molecule had been "selected by the Doherty as a tier 1 compound". The CSIRO and Doherty Institute said that tier 1 status did not mean a compound would show anti-viral activity against Sars-Cov-2, but it did mean they could pay the Doherty and CSIRO to have their technology tested.

What that meant in plain English was the tier 1 compounds did not include dog faeces or rocks. We thought the nonsense claims would end, but they didn't. Serious companies do the development work first and then announce it. Please, no more coronavirus news until you have run a large randomized controlled trial, and preferably won FDA or EU approval.

August began with good news. After 19 short biotech years Hatchtech won FDA approval for its Xeglyze single treatment for headlice – or specifically – their eggs, and 4D Medical opened up 98 percent in an oversubscribed \$56 million IPO for its four-dimensional (3-D over time) lung imaging, while the TGA approved Atomo's Covid-19 antibodies test.

Mesoblast had an FDA rollercoaster ride, tumbling on hard questions about remestemcel-L (the Osiris product for graft-versus-host disease), soaring on good answers and a nine-to-one vote, and later tumbling again on an FDA nyetski. Qbiotics announced a collaboration with Merck & Co for its EB46 tigilanol tiglate with Keytruda for unresectable melanoma, and the rest of the month was financial reporting.

Your R&D Tax Incentive Is Not Income

While it is not actually illegal to claim your Federal Government Research and Development Tax Incentive as revenue it is totally dishonest to do it. Your RDTI is NOT income, no matter what your highly-paid accountant or auditor says. So, stop doing it, or next year we shall start naming and shaming. It wastes our time and energy ploughing through the notes to an Appendix 4E to find that all the "revenue" is taxpayers' money. Just because ASIC and the ASX let you get away with it doesn't mean you are not deliberately misleading your shareholders. So, stop it.

And it would also be good if the ASX and ASIC made Australian companies listed on the Australian stock exchange report in Australian dollars, instead of pretending they are "global corporate entities" reporting in US dollars, Euros, Yuan or Shekels. That said, overall revenue was up on the previous year, as were the August BDI-40 and the ASX200.

Spring sprung with Opyl AI touting its artificial intelligence for Covid-19 results, which accurately predicted what Endpoints had been saying for months – that the lead vaccines were Moderna, Pfizer and Oxford-Astrazeneca, with the CSL-University of Queensland candidate not in its top 10, nor Russia's Gamaleya Sputnik V – despite President Vladimir Putin trying it on his daughter. Endpoints had Sputnik V at number six and UQ-CSL at 23.

Zelira had a collaboration for marijuana toothpaste, Clarity won FDA rare paediatric disease status for 64-copper Sartate for neuroblastoma, Elanco dropped its option with Pharmaust for Monepantel for cancer and Dimerix missed its diabetic kidney disease primary endpoint.

Cyclopharm had its 240-patient phase III Technegas lung imaging trial halted early ... but it was good news: with just 200 patients it had met its primary endpoint and was on its way to FDA approval, expected any time around or after April 2021.

Emerald changed its name to the less pronounceable Emyria, the TGA approved Starpharma's Vivagel for bacterial vaginosis and the company raised \$49 million, and the long-suffering Mark Diamond and Antisense won FDA rare paediatric disease status with the possibility of a "priority review voucher" (worth around \$100 million) for ATL1102 for Duchenne muscular dystrophy.

Mesoblast tumbled 45 percent on the FDA requiring another trial for GvHD despite the nine-to-one vote in favor. Most observers thought the company would be pinged on its ability to manufacture large consistent quantities of its stem cells, rather than the efficacy based on a single open label trial after Osiris had run large randomized controlled trials not showing efficacy.

MTP Connect released its second Covid-19 Impact Report saying the sector was recovering but faced "challenges". The US BARDA paid the privately owned Vaxxas \$31 million for its needle-free vaccine delivery system and Federal Treasurer Joshua Frydenberg dropped a plan to further diminish the widely approved Research and Development Tax Incentive, which would have cut funds to some of the most promising biotechs just when they needed it most.

On Monday October 12, the ASX went 'live' – or should we say 'dead' - with its "upgrade". Yes, a brand-new look with no way of accessing information or announcements. A truly brilliant feat by Marketing, which might have been better performed if IT was allowed to confer with what we call "users". The site is not as hopeless today as it was then, but it is still a pain in the proverbial and not user-friendly. And they were warned. Like the painter Arthur Boyd once said: "You can't tell anyone anything. They won't listen."

Well, not in marketing anyway. We are told that the ASX does pay attention to our comments and we have seen some very positive changes over the years. Basing the ASX advisers on industry rather than geography means they gain a much deeper understanding of the people and technologies.

The company formerly known as Phosphagenics, which changed its name to Avecho so we would forget that CEO Dr Esra Ogru stole \$6 million, reported that its tocopherol phosphate mixture version of vitamin E, mixed with marijuana made the cannabidiol more bio-available in rats. Lucky rats.

Biotech Daily thought the powerhouse board of Dr Greg Collier, Dr Ross Murdoch and Matt McNamara meant something very big would happen and just after we gave up waiting the share price doubled from 0.7 cents to 1.4 cents and 2.0 cents in December.

The ever-sharp TGA approved Clinuvel's Scenesse for erythropoietic protoporphyria (EPP) just four years after the EU and a year after the FDA, which finally, after a decade or so approved Pharmaxis Bronchitol for cystic fibrosis. Telix claimed a \$450 million deal with China Grand for radiotherapy. Let's hope that Anti-Trade Minister Simon Birmingham doesn't hear about it. Micro-X has a foot in both biotech and defence industries and won two US airport scanning contracts worth \$5.6 million – and a lot more if the pilot concept is successful.

CSIRO's Dr Cathy Foley was named as Dr Alan Finkel's successor as chief scientist and Victoria pledged \$155 million towards a \$550 million infectious diseases institute, while CSL set aside \$800 million for an influenza vaccine manufacturing facility. Impedimed scored a big win with Astrazeneca leasing 200 Sozos for bio-impedance measurement of body fluids including cardiac and Qbiotics won FDA approval for Stelfonta, or tigilanol toglate, for dog skin cancer. Paul Hopper planned a \$30 million Chimeric IPO for Car-T glioblastoma therapies. Auscann said it would acquire Cannpal and like the Bard1-Sienna acquisition we weren't sure why. Time will tell.

In late November, Imugene presented the strangest trial results we have ever seen, claiming statistical significance in a one-tailed p-value which came in at 0.08 which translates to a proper two-tailed p-value of 0.16 which is not actually significant even if "alpha" the predicted p-value is set at 0.10 instead of the usual 0.05 - meaning a 10 percent chance that luck or extraneous variables were at play. One can only use a one-tailed p-value if one is reasonably certain that the results can only be in one direction. That is, the compound will help not harm. And in cancer trials that is never certain.

December refused to go gently into the good night, much preferring a big bang theory than a weak Welsh whimper. The November BDI-40 entered record territory up \$2,303 million or 15 percent to a collective market capitalization of \$18,049 million.

Telix won an FDA "academic use" prostate cancer imaging approval and a TGA trial green light, Mesoblast's Remestemcel-L was fast-tracked in the US for Covid Ards, Hexima returned to the ASX, Control Bionics jumped 87 percent on its IPO for a muscle sensor that translates into computerized actions for the severely disabled, Resonance won FDA approval for its liver fat artificial intelligence diagnostic and Incannex graduated from marijuana to psychedelics for anxiety.

While the CSL-University of Queensland vaccine program was halted last Friday, it had significant successes along the way, as have all the serious vaccine and treatment developers. It's truly amazing what happens when you feed scientists.

Ellume struck marketing heaven, having applied for FDA emergency use for its single-use, rapid, home test for Sars-Cov-2 and claiming 96 percent accuracy last week, to shocking the tabloids with Wednesday's FDA approval. It was such good news that no one stopped to think about the implications and the ABC even chastened Australia's regulators for providing a free service.

While we applaud Ellume and CEO Dr Sean Parsons, who is actually going to buy a \$30 single use test when the State provides it for free? Americans, and they will need to be wealthy ones, at that.

Then Mesoblast announced the results of its seven year, 537-patient phase III trial of Revascor mesenchymal precursor cells for chronic heart failure saying the stem cells reduced cardiac events, but did not meet the primary endpoint of reducing hospital visits. It is possible that if Mesoblast had published actual data instead of demanding we trust their statistical analyses, the reaction might not have been so negative.

But the basic data was not there despite the good news that the stem cells reduced mortality. Percentages and “p” values are fine but we need to see the number of patients in each arm to validate the conclusions. Were they quoting the per-protocol or intent-to-treat numbers? Was it a subset or the total enrolled?

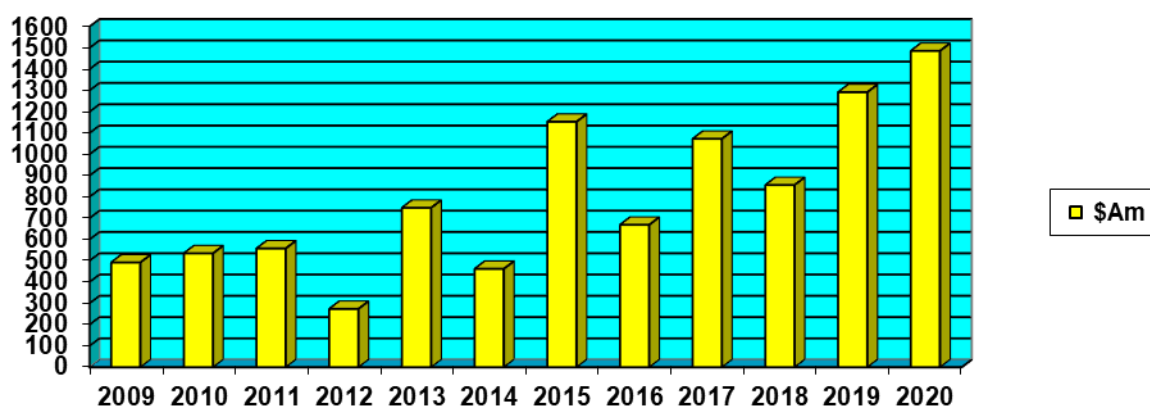
What we can say, unequivocally, is that seven years ago Mesoblast set a primary endpoint and on Tuesday said they had not met it. It’s not for us to instruct a multi-billion dollar company on how to do their public relations but try Launcelot Gobbo (there’s a name with which to conjure) for size: “Truth will out” (MoV; 2.2.78).

And that pretty much summarizes the year. In the end, the truth will come out.

IPOs

Nyrada won a mention in last year’s initial public offer list but technically it happened on January 16. Emerald (now Emyria) followed the next week, with Little Green Pharma, Atomo, Aroa, 4D Medical, Chimeric and Control Bionics all joining the ASX lists.

Capital Raisings 2009 -2020



Ending what many called a terrible and disastrous year for biotechs, not only is the BDI-40 at an all-time record high, so are capital raisings, up a healthy 15.0 percent on last year to \$1,486 million by the close of business today, not including Cochlear’s \$1.1 billion.

2020 AWARDS

(Judges: David Langsam, Marc Sinatra)

Chairman 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.

We are concerned with the gender-bias of the title, but have not found a neutral term for boss of the board. Suggestions are most welcome.

The Board Boss of the Year has been withheld this year, as the contenders are the winners from the past three years: David Williams, Paul Hopper and Sue MacLeman.

CEO of the Year

For the first year in a long time, the final selection was easy. Despite the very long short-list, we took no time to make the judgement.

There were many excellent runners-up, including Alcidion's Kate Quirk, Antisense's Mark Diamond, Atomo's John Kelly, Avita's Dr Mike Perry, Genetic Signatures' Dr John Melki, Next Science's Judith Mitchell, Polynovo's Paul Brennan, Pro Medicus's Dr Sam Hupert, Proteomics' Dr Richard Lipscombe and Volpara's Dr Ralph Highnam. Cochlear's Dig Howitt, CSL's Paul Perreault and Resmed's Mick Farrell all deserve special mentions.

But the 2020 CEO of the Year is unequivocally Telix's Dr Christian Behrenbruch for dancing on the double-edged sword of so many announcements that we were confused about which was the imaging agent and which was the treatment and unlike some companies we won't name, didn't need a trading halt for each and every one.

Telex has doubled in market capitalization in 2020 because it has the runs on the board. The company has struck deals and conducted research and development that make it the rising star of Australian biotech. Hell, it even has revenue!

Congratulations, Dr Behrenbruch. That will be a glass of shiraz, please.

Kamikaze of the Year

The competition in this space – primarily due to Covid-19 claims - has been terrific.

Both the Doherty Institute and the Walter and Eliza Hall Institute were in danger of damaging their credibility by selling their expertise to biotechs of variable quality, but that's just business, as the Corleones would say. The real culprits were those claiming to have cures or tests for The Virus and then failed to produce the goods. And there were many. But who actually crashed and burned this year?

A sliding share price is a warning sign but not definitive as we've seen with both Botanix and Osprey facing mortal danger but recovering, while Top 20 stock Avita went to the Nasdaq and had its market capitalization halved – which we said would happen – but the company is pretty much the same as before the dual listing.

Anteris' 100-to-one consolidation, following the then Admedus previous 10-to-one consolidation, hasn't held up its market capitalization which was down 58.5 percent in the year to November 30 to \$22 million.

Cellmid started the year at \$26 million fell to \$15 million in February, mentioned Covid-19 and tripled its value, raised \$6.3 million to a market capitalization of \$31 million but was back down to \$12 million at November 30 with negligible sales of its Chinese Covid-19 tests. Bluchiip slid from \$97 million to \$33 million and Cronos from \$32 million to \$6 million. But that's just the vagaries of biotech

The ASX lost Benitec to the Nasdaq, with GI Dynamics and Reva departing entirely. OBJ became 'Wellfully' and Genera was finally removed from the lists, but it was G Medical that promised big revenue and not a lot of delivery, but a huge pile of stock to founder Dr Yakov Geva. We think that was the best example of flying oneself into the ground.

Accounts department

Biotech Daily will have a small increase in the base rate for subscriptions in the New Year from \$1500 to \$1600. We have added staff to cope with the increased workload and have welcomed a rolled-gold guest columnist for the medical marijuana beat. Unfortunately, they want to be paid in money, not just glory. Or as the Legendary Jay Jerilderie McRoach once told me: "You can't eat prestige."

Summer holiday publishing schedule

Biotech Daily will shut down for the long, hot, Australian Summer tomorrow, December 18 and be back on deck refreshed and recharged on Monday January 18, 2021.

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, Rebekah Andrews, Rosann Anthony, Alice Lynch and Alex Langsam for all their superb work this year, not to mention the aforementioned rolled-gold guest columnist Peter Olszewski.

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 2021.

David Langsam
Editor

PRO MEDICUS

Pro Medicus says it has a \$18 million, five-year supply agreement with the Columbia, Maryland-based Medstar Health for its Visage 7 imaging technology.

Pro Medicus said Medstar was the largest health system in the Maryland and the Washington, DC metropolitan region, with 10 hospitals in the region.

The company said it would supply its imaging technology platform, including the Visage 7 Viewer, Visage 7 Open Archive and Visage 7 Workflow to all of Medstar's radiology and sub-specialty imaging departments, including the Washington DC-based Georgetown University Hospital.

Pro Medicus the product suite would be accessible through the Google internet cloud platform with rollout to begin by July 2021 and the first sites to be in use by October 2021. Pro Medicus chief executive officer Dr Sam Hupert said that "Medstar went through an extensive evaluation process including a pilot [program] that not only benchmarked Visage 7 compared to on-premises systems from other vendors, ... [but] served to verify the speed of Visage 7 in the public-cloud".

"Unlike systems from other vendors, Visage has been developed from the ground up for cloud deployment," Dr Hupert said.

"Traditionally, our clients have deployed Visage in their own private-cloud where all images are sent to a single, central server and streamed on demand from there," Dr Hupert said.

"This deal signifies a shift in the way US healthcare providers are now starting to think about public-cloud platforms," Dr Hupert said.

"In addition to [the internet] cloud, Medstar was keen to pursue a single-vendor solution which, with our expanded product portfolio, we are able to deliver across their health network", Dr Hupert said.

"We see this and the move to public-cloud as two key initiatives that will broaden our addressable market in North America allowing us to leverage our rapidly growing footprint in this region," Dr Hupert said.

Pro Medicus was up \$1.03 or 3.3 percent to \$32.15 with 414,106 shares traded.

MICRO-X

Micro-X says it has a \$1.3 million agreement with the Australian Defence Force for its Rover mobile x-ray for the ADF's Deployable Health Capability Program.

Micro-X said the Rover system aimed to deliver a transportable health capability to support Australian overseas military operations, humanitarian aid and disaster relief.

Micro-X managing-director Peter Rowland said the company was "excited that our Rover is set to enter operational service with the Australian Defence Force".

"We've had enormous interest in Rover from military forces world-wide because no other product offers such high performance in such a lightweight package", Mr Rowland said.

Micro-X was up three cents or 8.45 percent to 38.5 cents with 1.4 million shares traded.

RACE ONCOLOGY

Race says it has received \$387,384 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Race said the rebate related to expenditure for the year to June 30, 2020.

Race was up nine cents or 5.1 percent to \$1.87.

IMUGENE

Imugene says it has completed enrolment of the first cohort of three patients in its 32-patient, phase I, dose-escalation trial of PD1-Vaxx for non-small cell lung cancer.

Earlier this month, Imugene said it has dosed the first patient in the first-in-human trial of the PD1-Vaxx checkpoint immunotherapy candidate in Melbourne and was recruiting non-small cell lung cancer patients to test three different doses PD1-Vaxx, with at least three patients in each cohort (BD: Dec 1, 2020).

Today, the company said the primary goal of the phase I trial was to determine safety and an optimal biological dose of PD1-Vaxx as a monotherapy and would measure efficacy, tolerability and immune response.

Imugene managing-director Leslie Chong said the start of the study “with the first patient dosed in Australia just 18 days ago was a significant milestone for Imugene and clinicians treating Australians faced with the challenge of lung cancer”.

Imugene was unchanged at 9.9 cents with 30.8 million shares traded.

ORTHOCELL

Orthocell says its Celgro for tissue repair has passed an Australian Therapeutic Goods Administration review and expects market authorization by April 2021.

Orthocell said the TGA had completed the conformity assessment review of the company’s application and confirmed that its collagen-based Celgro complied with the requirements of the medical device regulations with respect to the safety and performance in dental bone and tissue regeneration procedures.

The company said the conformity assessment included a review of Orthocell’s quality management system and manufacturing processes.

Orthocell said it applied for Celgro to be included on the Australian Register of Therapeutic Goods and expected market authorization for dental bone and tissue regeneration procedures to be granted by March 31, 2021.

The company said it had applied for Celgro to be included on the ARTG prostheses list, which would enable reimbursement by insurers, and hoped to be approved by 2022.

Orthocell managing-director Paul Anderson said the conformity assessment was “an important milestone for the company as we continue to commercialize our collagen medical device platform and I am excited to complete this important step towards gaining Australian and US [Food and Drug Administration] regulatory approval”.

Orthocell was up one cent or 2.4 percent to 43 cents.

MEDADVISOR

Medadvisor says its shortfall placement at 38 cents a share has raised about \$4 million, taking the total to about \$42.2 million, and it has signed two new contracts.

Last month, Medadvisor said had raised \$35 million in a placement and institutional rights offer to acquire Adheris Health, and this month its retail rights offer raised \$3.2 million of a hoped-for \$20 million, taking the total to \$38.2 million (BD: Nov 12, Dec 4, 2020).

Today, the company said that through its subsidiary Adheris, it had secured a \$US3.4 million (\$A4.7 million) five-month vaccine contract to inform Adheris’ 180 million patient network of the correct and safe adherence to vaccines.

Medadvisor said the contract was with an existing unnamed client.

The company said it had signed a \$1.8 million, one-year deal with an existing unnamed pharmaceutical company client for its Medadvisor medication management software.

Medadvisor was up one cent or 2.8 percent to 37 cents.

THC GLOBAL GROUP

THC says it has raised \$2.75 million in a placement at 25 cents a share to develop its Medimar platform and increase its medical marijuana manufacturing.

THC said the price was a 7.3 percent discount to its last closing price and in a presentation said Medimar was an online platform designed to connect patients, prescribers, and pharmacies with electronic commerce distribution.

The company said it would use the funds to increase and expand production at its Queensland-based Southport manufacturing facility to include marijuana-based vaporizer liquids, hard gelatine capsules, suppositories, ovules and creams.

THC was unchanged at 27 cents with 1.85 million shares traded.

NEUROTECH

Neurotech says it hopes to raise \$366,000 in a placement at 2.2 cent a share, and will grant 38,000,000 options to chair Brian Leedman, Max Capital, and two directors.

Neurotech said the placement offer would open on December 16, 2020 and close on January 15, 2021 and Mr Leedman would apply for \$50,000 worth of shares.

The company said it would issue 20,000,000 options to Mr Leedman as remuneration for services to the company, with half exercisable at 1.5 cents each and the remaining exercisable at two cents each by October 31, 2023, with 10,000,000 options for Max Capital for acting as lead manager to the raising and providing advisory services, exercisable at three cents each within two years.

Neurotech said directors Mark Davies and Winton Willesee would be granted 4,000,000 options each for services, exercisable at 3.8 cents each by November 30, 2023.

Neurotech said it would not raise any funds from the issue of options to Mr Leedman, Max Capital, Mr Davies or Mr Willesee.

Neurotech fell 0.2 cents or 3.45 percent to 5.6 cents with 15.1 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says the US Patent and Trademark Office has granted a patent relating to three biomarkers of its Colostat colorectal cancer diagnostic.

Rhythm said the patent, titled 'Diagnostic for Colorectal Cancer', would protect its intellectual property until July 14, 2031.

The company said it had patents for Colostat in the US, Australia, China, Japan, the UK, and Europe with patent applications pending in Brazil and India.

Rhythm was up 1.5 cents or 1.9 percent to 81.5 cents with 1.6 million shares traded.

IMMUTEP

Immutep says it is increasing the manufacturing of its IMP321, or eftilagimod alpha, for cancer at the Mashan, China-based Wuxi Biologics manufacturing plant.

Immutep said it planned to increase the IMP321 manufacturing process "from 200 litres to 2,000 litre capacity bioreactors".

Immutep chief executive officer Marc Voigt said that following very encouraging interim overall survival data last week "we have activated our plans to upscale the manufacturing of Efti to 2,000L single-use bioreactors to prepare for potential commercial manufacturing and potential registration trials in multiple indications" (BD: Dec 10, 2020).

Immutep fell one cent or 2.3 percent to 42 cents with 4.6 million shares traded.

TELIX PHARMACEUTICALS

FIL Investment Management says it has increased but been diluted in Telix from 19,743,750 shares (10.00%) to 24,978,764 shares (8.91%).

The Hong Kong-based FIL said that between July 2, 2018 and December 11, 2020 it bought and sold shares at prices ranging from 66 cents to \$4.20 a share.

Telix was up 15 cents or 4.2 percent to \$3.71 with 539,219 shares traded.

EMVISION MEDICAL DEVICES

Emvision says Uniquist has ceased its substantial shareholding in Emvision, selling 4,800,000 shares and retaining 1,200,000 shares or 1.70 percent of the company.

Emvision said 6,000,000 shares were issued to Uniquist at part consideration for an intellectual property licence agreement and assignment deed for acquiring the rights for the portable medical imaging technology (BD: Jan 21, 2018).

The company said the 4,800,000 shares sold by Uniquist had "been purchased by existing institutional shareholders and other existing and new shareholders".

Emvision said Uniquist intended to maintain its shareholding "for the foreseeable future".

Uniquist said that on December 16, 2020 it sold the 4,800,000 shares at \$2.727 a share "via special crossing".

Emvision was up seven cents or 2.3 percent to \$3.10.

ACRUX

Acrux has requested a trading halt "pending an announcement regarding a capital raising".

Trading will resume on December 21, 2020 or on an earlier announcement.

Acrux last traded at 18.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says it will release 6,606,225 restricted shares from voluntary escrow on December 24, 2020, with no further shares in voluntary escrow.

Visioneering said the restricted shares were part of the 19,818,660 shares issued to employees in May in lieu of cash remuneration.

According to Visioneering's most recent Appendix 2A, the company had 993,725,559 shares on issue, including the 6,606,225 voluntary escrow shares.

Visioneering was up 0.1 cents or 4.2 percent to 2.5 cents.

ANTERIS (FORMERLY ADMEDUS)

Anteris says the Hong Kong-based Star Bright Holding's representative Dr Yanheng Wu has resigned as non-executive director, effective from December 15, 2020.

In 2018, the then Admedus said it had appointed Hong Kong's Constellation International managing-director Dr Wu to represent Star Bright, which at the time held 19.99 percent of the company (BD: Sep 17, 18, 2018).

In July, Star Bright said it reduced its holding in Anteris to 730,192 shares (12.35%), taking a loss and in September, Constellation said it had ceased its substantial holding in Anteris, reducing to 259,699 shares (4.39%) (BD: Jul 17, Sep 21, 2020).

Today, Anteris said Du Wu's resignation was "due to other commitments".

Anteris was up four cents or 1.05 percent to \$3.84.

EMVISION MEDICAL DEVICES

Emvision says it has appointed magnetic resonance imaging specialist Prof Stuart Crozier as chief scientific officer.

Emvision said Prof Crozier had co-invented its technology as well as signal correction technology that corrected magnetic field distortions to produce faster, clearer and more accurate images, without adding to the cost of the magnetic resonance imaging machines. The company said Prof Crozier's technology was licenced to Seimens and GE Healthcare, and he was awarded the Clunies-Ross award for his contributions to the MRI field.

Emvision said that Prof Crozier was previously the director of biomedical engineering at the University of Queensland.

PRESCIENT THERAPEUTICS

Prescient says it has appointed haematologist and blood cancer researcher Prof Henry Miles Prince to its scientific advisory board.

Prescient said Prof Prince was a professor at Melbourne's Monash University and the University of Melbourne, and was involved in research programs involving genomics, stem cell research and the mechanism of the immune systems control of blood and cancer growth, including working as the lead investigator of the company's phase I trial of PTX-100 for cancer.

The company said Prof Prince was the chair of the Medical Scientific Advisory Group of Myeloma Australia, Director of Molecular Oncology and Cancer Immunology at Epworth Healthcare had published more than 450 journal articles.

According to his LinkedIn page, Prof Prince holds a Bachelor of Medicine and Bachelor of Surgery from Monash University.

Prescient was up 0.4 cents or 6.45 percent to 6.6 cents with 3.7 million shares traded.