Biotech Daily

Thursday December 19, 2019

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PARADIGM UP 9%; PHARMAXIS DOWN 6.5%**

*** 2019 – BIOTECH DAILY'S YEAR IN REVIEW**

*** CARDIEX $1.9m BAYER TRIAL CONTRACT**

*** RESAPP TO TEST ABORIGINAL COPD**

*** IMMUTEP RECRUITS 2nd COHORT FOR IMP321 SOLID TUMOR TRIAL**

*** ALCIDION $500k TAUNTON, SOMERSET NHS PATIENTRACK DEAL**

*** NEXT SCIENCE APPOINTS TRIAD AS TORRENTX US DISTRIBUTOR**

*** EMVISION BRAIN SCANNER READY FOR CLINICAL TRIALS**

*** MEMPHASYS SHIPS FIRST BATCH OF FELIX DEVICES**

*** ANATARA: 'GARP ENHANCES ANTI-INFLAMMATORIES IN MICE'**

*** CANN GROUP, IDT 1st COMMERCIAL MARIJUANA PRODUCT**

*** CANN GLOBAL, KOEGAS SOUTH AFRICA MARIJUANA J-V**

*** PALLA NEGOTIATES BETTER LOAN TERMS**

*** CYCLOPHARM REQUESTS CAPITAL RAISING TRADING HALT**

*** JAMBER TAKES 12% OF CRESO**

*** MGC SHIPS MARIJUANA COGNICANN FOR DEMENTIA, ALZHEIMER'S**

*** THC APPOINTS ANGELA MACQUIRE COO**

*** BOD ALTERNATIVE DIRECTOR STEPHEN THOMPSON RESIGNS**

MARKET REPORT

The Australian stock market fell 0.27 percent on Thursday December 19, 2019, with the ASX200 down 18.3 points to 6,833.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and four were untraded. All three Big Caps fell.

Paradigm was the best, up 25 cents or 9.1 percent to $3.00, with 1.3 million shares traded. Antisense climbed 8.1 percent; Next Science improved 6.9 percent; Impedimed improved 5.7 percent; Avita was up 4.1 percent; Compumedics, Mesoblast and Oncosil were up more than three percent; Resonance rose 2.4 percent; Neuren and Orthocell were up more than one percent; with Clinuvel, Kazia, Pro Medicus and Volpara up by less than one percent.

Pharmaxis led the falls for the second day in a row, down one cent or 6.45 percent to 14.5 cents with 3.3 million shares traded. Actinogen and Prescient lost more than five percent; Uscom fell 4.2 percent; Immutep, Medical Developments and Telix shed two percent or more; CSL, Cynata, Genetic Signatures and Polynovo were down more than one percent; with Cochlear, Nanosonics, Resmed and Starpharma down by less than one percent.

BIOTECH DAILY EDITORIAL: 2019 - THE YEAR IN REVIEW

The three Big Caps – Cochlear, CSL and Resmed began the year with increased revenues … but so did Airxpanders.

Osprey said it would breakeven by 2022, giving it plenty of time to do so and its Appendix 4Cs indicate it is heading in the right direction, which just happens to be opposite to its share price. Prana formally became Alterity as Boston Life Biosciences took the reins to continue development of PBT434 for Parkinson's disease.

Neurotech came unstuck when a former employee sued founder Dr Adrian Attard for breach of copyright and it emerged from Malta that Dr Attard didn't have the qualifications he claimed.

Reva and Genera went hunting funds, but with little success, both eventually dropping off the ASX radar, along with Airxpanders.

Next Science raised $35 million in its ASX public offer for its anti-biofilm technology and a few months later earned a place in the BDI-40.

The former Polartechnics, rebadged as Truscreen, re-emerged from a 10-year hiatus in New Zealand with an all new and improved cervical cancer screen but has struggled to gain traction despite a good story.

Telix made a series of complicated announcements about its technology, technical partners, manufacturing and licencing, that when one drilled down, turned out to be good news, as compared to some deeply technical announcements, especially from Noxopharm, that provided very strong evidence that its NOX66 with radiation may or may not have helped one patient in 25 have a partial remission, described as a "66 percent success rate". But Neuroscientific won the intellectually impenetrable announcement award for 'CVN Model Indicates Neuroprotective Properties of Emtin-B'.

Oncosil hit a roadblock at the end of March, tumbling 87 percent on European doubts about the clinical benefit – or otherwise – of its pancreatic cancer radiation treatment. The company has continued to seek EU approval, submitting an updated CE mark report in November.

The early April Federal Budget continued its time-honored tradition of cutting funding to the biotech sector, with a further $1,316 million axed from the five-year estimates.

Paradigm surprised the market with a mid-April $78 million capital raise on the back of its 2018 phase IIb trial of pentosan polysulfate sodium for knee osteoporosis pain. It stood as the single largest biotech capital raise this year, with a Mesoblast $75 million placement, just behind it, until Avita raised a very cool $120 million in November.

In May, Actinogen joined the very large club of companies proving their drugs don't work for Alzheimer's disease, falling 71 percent on the news and later recovering a little with news of the viability of a stronger dose of Xanamem.

The US Food and Drug Administration approved LBT's APAS Independence giving the very long-suffering company a kick-start, which was followed, eventually, with CE mark approval and its first sale in Europe.

Phosphagenics finally succeeded in renaming itself, not the 2015 Alyptus, but Avecho Biotechnology, so everyone could forget that former chief executive officer Dr Esra Ogru stole $6 million and went to gaol, along with Dr Woei-Jia Jiang and Dr Robert Gianello, way back in 2014.

Phylogica renamed itself PYC Therapeutics for no obvious reason and Shareroot became Opyl, for more obvious reasons.

BTC surprised many with its acquisition of the Admedus infusion business as the latter went about fixing its finances after an apparent falling out with its Hong Kong investors, who decided they no longer wanted to stump up the money for the lucrative but very high risk-reward vaccines business of Prof Ian Frazer, in a deal guaranteeing Admedus chief executive officer Wayne Paterson as chairman for a minimum of five years.

Mid-year was not good news for Benitec with Axovant terminating the very promising $954 million BB-301 for ocular-pharyngeal muscular dystrophy deal. From a "milestone" for the company it quickly moved to "more optimization required". The 'Update' headline was uninformative, but at least Benitec admitted in the first sentence that the licence had been terminated, rather than the usual obfuscation of "We've taken back total control of our compound" favored by some public relations spinners. Despite considerable cash in the bank, management has decided to move the company to the US, where everything is much more expensive, and where they raised all of $US2.25 million in "pre-paid warrants".

Also in June, Zoetis terminated the previously much vaunted licence to Anatara's Detach for pig and livestock diarrhoea.

There was internal trouble at Genetic Technologies with director Samuel Xue Lee requiring a set of training wheels when it came to selling his entire stake in the company in a closed period and forgetting to tell anyone. Mr Lee later left and the company had a change of senior board and management.

The marijuana companies began telling us how many scripts had been issued each month, and Bod Australia came up with what looked like a clinical trial, but turned into a pay-to-play observational study.

The reason that journalists don't pay sources or courts pay witnesses is that the funding may corrupt the evidence. If you pay someone to say something, they will say what you want them to say. One imagines it might be the same in a very subjective trial of marijuana for anxiety.

But Bod was not alone. The idea of selling places in a trial caught on quickly, with Medlab also offering a 2,000 patient 'observational study'.

In June, unsurprisingly, Bionomics BNC210 also failed its agitation trial endpoints, just like its earlier PTSD endpoints and later sold off its revenue-generating French assets.

As the financial year came to a close, Novita struck a deal with the Victoria Government for its Tali attention deficit test, and Starpharma launched its Betadine bacterial vaginosis treatment in Europe.

On July 1, we posted that the 13-year BDI-40 was up 339 percent, the Big Caps were up 681 percent, with the benchmark ASX200 up just 30 percent over 13 years.

Former Sirtex chief executive officer Gilman Wong pleaded guilty to insider trading, with the sentencing due for early next year.

Samsung bid $82.5 million for Nuheara but it wasn't enough and the deal disappeared. Cynata was offered $204 million by Sumitomo Dainippon and that disappeared, too. Alchemia, once a blood thinning and anti-cancer company became Australian Primary Hemp.

Imugene acquired Vaxinia for its CF33 for cancer, adding to its anti-cancer pipeline. Along with Amplia, Immutep, Kazia, Mesoblast, Neuren, Phylogica, Prescient and a raft of other companies, continued the arduous trek towards advanced trials and hopeful registration, releasing important but less newsworthy announcements.

These companies should not be overlooked. It's cranium down and gluteus maximus up. Clavicle to the wheel and proboscis to the grindstone.

Dissident shareholders failed to take over Factor Therapeutics but appear to have blocked poker machine operator Bruce Mathieson Snr at Respiri, which has had more board and management changes than any other biotech.

Orthocell claimed that its Celgro repaired nerve damage in rats and later backed it up with human evidence, impressing the markets and investors.

Opthea gave August a kick-start with a 160 percent share price jump on its long-awaited – but under-budget and under-time – 366-patient, phase IIb trial of OPT-302 for wet age related macular oedema. Opthea climbed 160.1 percent from 86.5 cents to $2.25, closing the day at $2.06 and hitting a 52-week high of $4.15 on September 2, before finding a "more realistic valuation", as they say, around $2.80.

In the private world, Melbourne's Medicines Development for Global Health was paid somewhere around $150 million by Novo Nordisk for its FDA priority review voucher for moxidectin for river blindness. The actual number has not been disclosed by either party but the developer of the voucher system says recent vouchers have changed hands at around $US100 million.

Cochlear, CSL and Resmed continued their very boring full year results: record revenue, record profits, record share price, record market capitalization, record research and development spend. Just like a broken record, only brilliantly profitable.

Less profitable, the ASX suspended Admedus, Airxpanders, Genera, Invitrocue and Reva for failing to pay annual listing fees. Admedus and Invitrocue came back, the others didn't.

Mesoblast opened the Spring carnival with Grünenthal paying up to $220 million to licence MPC-06-ID stem cells for back pain, making older readers sit up in pleasure, the FDA cleared Paradigm's PPS for compassionate use for knee osteoarthritis pain and Starpharma added DEP-irinotecan to its pipeline.

But Fujifilm's big cheque for Cynata's CYP-001 for graft versus host disease disappointed punters, coming home with $67 million, when some hoped it would be $670 million.

Actinogen bounced into October with a 467 percent jump, from a very low base, to 5.1 cents on news that a stronger dose of Xanamem for Alzheimer's disease improved cognition in healthy volunteers with statistical significance, something the 186-patient Xanadu trial failed to do in May. Biotech Daily salutes CEO Dr Bill Ketelbey and the Actinogen team for diligently continuing where others might have simply given up.

The next day, the chooks came home to roost for Chris Collins, with the Trump-supporting Congressman pleading guilty to insider trading charges and resigning from the House of Representatives for telling his son and others to sell their Innate Immunotherapy shares following the failure of MIS416 for multiple sclerosis, but before the ASX was informed.

Then came tragedy. Former QRX chief executive officer Dr John Holaday was shot by a stray bullet from one of the millions of guns the US allows on its streets, in a deliberate misunderstanding of the 18th Century constitutional right to bear single-shot, wildly inaccurate muskets. This writer has always opposed civilian gun ownership and along with all the mass murders this year, the pointless death of Doc Holaday was deeply saddening.

The FDA finally approved Clinuvel's Scenesse for erythropoietic protoporphyria, pushing shares a further 63 percent to $45.88 each.

Not to be outdone, Orthocell chimed in with Celgro and microsurgery restoring voluntary movement to 24 of 25 nerve repairs in 12 patients. Orthocell only climbed 20 percent.

Starpharma added DEP-gemcitabine to its cancer pipeline, this one for pancreatic cancer, and the Israel-based, Nasdaq-listed Redhill showed what can be done with Australian inventions when we don't stump up the funds, winning FDA approval for Talicia, formerly Sydney's Heliconda, for helicobacter Pylori. Well done, Prof Tom Borody and Redhill.

Proteomics won CE mark for Promarkerd for diabetic kidney disease, Avita stunned with a $120 million raise and Burnet Institute director Prof Brendan Crabb won the $80,000 Glaxosmithkline and Research Australia gong for work on the DNA of the malaria parasite.

As the year came to a close, former Cyclopharm chair Vanda Gould was gaoled over a matter involving the Australian Taxation Office, the Federal Police and the Australian Securities and Investments Commission raided the offices of the Regal Funds investment house which is, or has been, substantial in about a dozen biotechs, and Ellex announced it was selling off the bit of the company responsible for 80 percent of its revenue.

Starpharma posted "efficacy signals" from its 14-patient, phase I trial of DEP-cabazitaxel for solid tumors taking it to a phase II trial, with Qbiotics showing EBC-46 tumor safety and efficacy in a 22-patient trial.

Polynovo won CE mark for its CSIRO-invented Novosorb and announced that it was providing the bio-resorbable skin product for burns patients from the New Zealand White Island volcanic eruption.

And in the last working week of the year, Antisense jumped 46 percent on news that ATL1102 showed efficacy in a nine-patient trial for Duchenne muscular dystrophy, while Pharmaxis tumbled 42 percent on Boehringer Ingelheim terminating the BI1467335 (PXS4728A) NASH program, but keeping it for diabetic retinopathy.

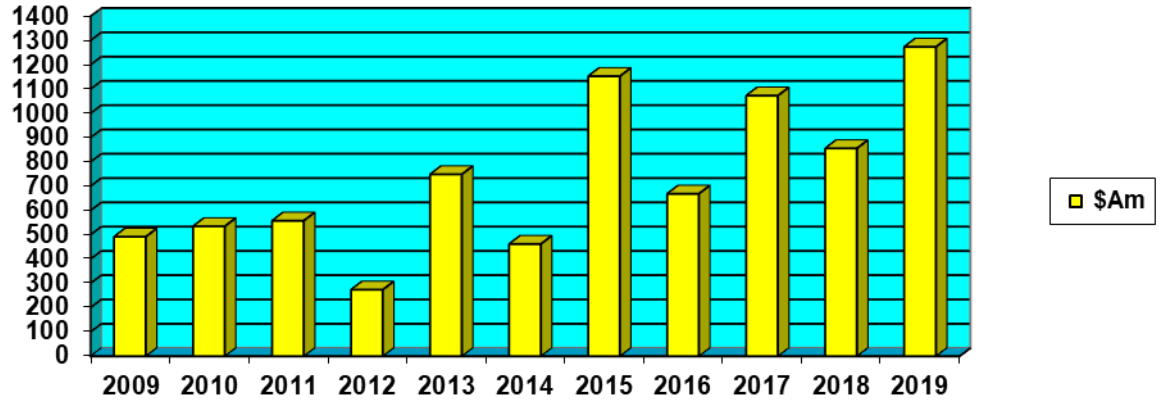
We ended the year on a very high note. For the 12 months to November 30, the Biotech Daily Top 40 Index (BDI-40) was up 114.3 percent, compared to the benchmark ASX200 up 20.8 percent, the three Big Caps up a collective 55.9 percent and the Nasdaq Biotechnology Index up 11.4 percent.

As previously mentioned, the 18 companies making up Cannabis Corner, received more 'realistic valuations' of a combined value of less than $1 billion, down from the July 31 high of $1,913 million.

IPOs

There were some very serious initial public offers and a few respectable small ones. Emvision, Heramed (Dec 2018), Shareroot/Opyl, Next Science, Invex, Osteopore, Cronos and Nyrada have all joined the team, with Koligo, Emerald Clinics, 4DX and Ellume among the others expecting to do so, shortly.

Capital Raisings 2009 -2019



2019 was an excellent year for raising money. A total of 82 companies have raised $1.27 billion – a 10-year record - with several undertaking two capital raises in the year.

None of the money was raised by the three Big Caps of Cochlear, CSL and Resmed and just two of the raises were by marijuana companies.

RDTI changes opposed by Ausbiotech, Medicines Australia

The latest Federal Government announcement to further cut and change the Research and Development Tax Incentive, instead of vetting the claimant companies, means that along with clean tech and information technology, biotech will have its funds cut, again.

Both Medicines Australia and Ausbiotech have attacked the Federal Government for its Christmas present of more mis-directed RDTI cuts.

What is required for better targeting of competing resources is not caps, cuts and "intensity" jargon, but an Independent Innovation Board to vet the claims - people who know the industries and can tell the difference between a cancer molecule and a road to a mining camp.

And the entire research and development budget comes nowhere near that for obsolete submarines and F-35 'strike fighters'.

We have seen near continuous announcements of funding from the Medical Research Future Fund with a drip feed of small grants, which previously would have been announced as a large group of companies or research institutes winning a considerable amount of money, but has been repackaged as individual announcements, and most bizarrely, sometimes over the weekend when no one is watching.

There are question marks over the funding of the Australian Research Council, Commonwealth Scientific and Industrial Research Organisation and National Health and Medical Research Council and whether some of their money is being spent through the MRFF.

Bank of New York Mellon and Nominee Companies

In May, ASIC required the Bank of New York Mellon (and others) to continuously lodge totally meaningless change of substantial shareholder notices. The rule is bizarre and misdirected.

Biotech Daily strongly supports transparent share ownership and every company should list all of its shareholders and not allow anyone to hide behind nominee companies or private companies acting for superannuation funds.

The new ASIC rule means the ASX announcements page is filled with meaningless substantial shareholder notices, while not telling anyone who their co-investors really are. It's a disgrace.

ASIC has repeatedly told Biotech Daily that hiding behind nominee companies is a matter for Trust law and the Commission can do nothing about it.

But Treasurer Joshua Frydenberg and Finance Minister Senator Mathias Cormann can. So, would you please amend the law so that people cannot hide their identity when they buy shares in Australian publicly-listed companies?

2019 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 apart from “convener” can’t come up with a gender-neutral term for boss of the board. “Chair”, “chairwoman” and “chairperson” all just sound wrong. Alternative suggestions are most welcome.

Nevertheless, the Board Boss of the Year must be awarded to one who has many boards. From MTP Connect, Anatara and Novita to directorships with Palla Pharma, Oventus, Reproductive Health Sciences and Veski, this year’s award goes to Sue MacLeman.

Well-earned, Ms MacLeman.

CEO of the Year

Each year the selection seems harder and harder. The short list was already a long list and when we carved it into a very short list, it still makes lengthy reading.

Antisense’s Mark Diamond has already won his award for longest-serving biotech CEO, and this week, finally had some real success to crow about, again. (ATL1102 showed efficacy for multiple sclerosis, a decade ago, but it never progressed.) Genetic Signatures’ Dr John Melki, Proteomics’ Dr Richard Lipscombe, Volpara’s Dr Ralph Highnam and Telix’s Dr Christian Behrenbruch have made very serious progress, as have Alcidion’s Kate Quirk, Next Science’s Judith Mitchell and Avita’s Dr Mike Perry, along with last year’s winner, Pro Medicus’s Dr Sam Hupert.

The very very short list came down to CSL’s Paul Perreault, Polynovo’s Paul Brennan, and Clinuvel’s Dr Philippe Wolgen, who won the award two years ago for EU Scenesse approval and this year won US FDA approval. Gee, you make it hard.

But the consensus is that the 2019 CEO of the Year is Opthea’s Dr Megan Baldwin for taking a very difficult drug down a very difficult path and producing excellent results.

Congratulations, Dr Baldwin.

Kamikaze of the Year

The competition in this space has been tremendous. While there have been quite a few Darwin award winners vying for space among the lemmings, there have been several stand-outs.

Last year’s winner, Admedus and chief executive officer Wayne Paterson, were certainly in the running, spending much of the year in an extended suspension and selling off just about all the family silver.

A close runner up was Bruce Mathieson's Respiri (formerly Karmelsonix and Isonea) changing directors and CEOs at a very alarming pace until Nick Smedley and Marjan Mikel took control a month ago and calmed the horses. Reva, Airxpanders, Adherium, Medibio and Genera have all had enough issues to qualify, but the undisputed winner must be the once-promising antisense developer Benitec.

Benitec completed its 15-year spiral dive from failing in HIV, hepatitis C, head and neck cancer (announced at 6pm as we broke up for last Christmas), and ocular-pharyngeal muscular dystrophy - which is a bad run forgivable in the world of clinical trials - to become something of a cashed-up shell.

With no new science announced this year, but $24.6 million in the bank at September 30, Benitec will follow Biota to the US, where we wish it somewhat better success.

Accounts department

Biotech Daily will have a small increase in the base rate for subscriptions in the New Year from $1450 to $1500, in part a coincidental recognition of our 15th year of publication, while the 10 percent discount for industry organization members will cease, reducing the back office work-load.

Summer holiday publishing schedule

Biotech Daily will shut down for the long, hot, Australian Summer tomorrow, December 20 and be back on deck refreshed and recharged on Monday January 20, 2020.

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 shall 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, Alice Lynch, Tobias Serr-Li 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, a Happy Channukah, Summer Solstice and Hogmanay/New Year and see you all in 2020.

David Langsam
Editor

CARDIEX

Cardiex says it has a $1.9 million, 15-month clinical trial contract with Bayer AG for central blood pressure clinical trial services for a vascular disease study.

Cardiex said it expected to receive $US1.275 million ($A1.9 million) in revenue from the Leverkusen, Germany-based Bayer over the study period, starting in April 2020, at up to 50 sites in Europe and the US.

The company said the study would use its Xcel central blood pressure monitoring device and Oscar 2 24-hour ambulatory blood pressure monitoring device, powered by its Sphygmocor blood pressure monitoring technology.

Cardiex chief executive officer Craig Cooper said, “this new contract with major pharmaceutical and life sciences company Bayer AG is further recognition of the global importance of our technology for the diagnosis and monitoring of vascular disease”.

“Whereas previous contracts have focused on cardiovascular trials, we are now actively expanding our marketing efforts to cover a wider range of clinical trials that need monitoring of vascular health, such as diabetes, Alzheimer’s and related disorders,” Mr Cooper said.

Cardiex was up 0.1 cents or 3.45 percent to three cents with 7.1 million shares traded.

RESAPP HEALTH

Resapp says the Western Australian Aboriginal Health Ethics Committee has approved a pilot study of its chronic obstructive pulmonary disease screening.

Resapp said the six month, 200-patient, double-blind study would carry out full clinical and spirometric assessments at the Rangeway, Western Australia-based Geraldton Regional Aboriginal Medical Service.

The company said it would compare results from its smartphone application, which analyzed patient cough sounds to identify chronic obstructive pulmonary disease (COPD), to the final clinical diagnosis.

Resapp said that diagnosis of COPD was based on a combination of self-reported symptoms and measurement of lung function by spirometry, which was unavailable in many remote communities.

Resapp fell 1.5 cents or 5.9 percent to 24 cents.

IMMUTEP

Immutep says it has begun recruitment of the second cohort of six patients for its phase I trial evaluating 30mg IMP321 with avelumab for advanced solid malignancies.

Immutep said no safety signals or dose limiting toxicities had been reported from the six cohort one patients, who had been fully recruited and had received a standard dose of the avelumab and 6mg of IMP321, or eftilagimod alpha.

The company said one of six patients had a partial response and it expected more data by July 2020.

Immutep said the Insight-004 study was the fourth arm of the 12-patient Insight trial, conducted by the Frankfurt, Germany-based Institute of Clinical Cancer Research under its collaboration with Merck KGaA and Pfizer Inc to evaluate the safety, tolerability and recommended phase II dose of IMP321 with avelumab for advanced solid malignancies.

Immutep fell half a cent or two percent to 24.5 cents.

ALCIDION GROUP

Alcidion says it has signed a three-year, $500,000 agreement with Taunton and Somerset National Health Service Foundation Trust to deliver its Patientrack system.

Alcidion said Taunton and Somerset NHS would use Patientrack to capture patient observations and deploy electronic patient assessments, including sepsis, neurological, neurovascular, weight and Bristol stool assessments, to improve patient care and safety.

The company said that Patientrack would "inter-operate with other hospital systems to deliver vital information where needed".

Alcidion chief executive officer Kate Quirke said the NHS was her company's "biggest customer base in the world".

"This is an important opportunity for us to expand our work within a globally respected institution and to put helpful technology and information into the hands of professionals, where it can really make a difference," Ms Quirke said.

Alcidion fell one cent or 5.4 percent to 17.5 cents.

NEXT SCIENCE

Next Science says it has a five-year exclusive US distribution agreement with Triad Life Sciences for its Torrentx wound wash.

Next Science said the Memphis, Tennessee-based Triad Life Sciences would promote, market, distribute and sell Torrentx for wound care in the US for emergency rooms, doctors' offices, ambulances, pre-hospital treatment rooms and for in-home treatments.

The company said Triad would sell non-exclusively an over-the-counter version until it received US Food and Drug Administration 510(k) clearances, expected by October 2020, when it would be sold alongside Triad's skin substitute product under the Tridentx brand.

Next Science was up 12 cents or 6.9 percent to $1.85 with 598,898 shares traded.

EMVISION MEDICAL DEVICES

Emvision says has completed functional and electrical safety testing and key checks for its brain scanner unit to begin clinical trials.

Emvision said the Princess Alexandra Hospital biomedical engineering department had performed the testing and it had completed all necessary training and would test newly fabricated clinical units on several healthy volunteers.

The company said it had demonstrated progress on the imaging algorithms to establish a solid imaging baseline, which would support a single centre, six-month, 30-patient trial of its brain scanner, with confirmatory computed tomography (CT) and magnetic resonance imaging (MRI).

Emvision said the primary objective of the trial would be to collect imaging data from stroke patients, to allow for refinement and selection of optimal imaging algorithms and for early data on correlation with CT and MRI scans.

The company said it expected to receive administrative approval to begin patient scanning shortly.

Emvision chief executive officer Dr Ron Weinberger said that "to enter the clinic, on schedule, with a breakthrough technology like ours, is an exciting milestone".

"The clinical trial will provide us with valuable learnings and enablement to explore the potential of our technology for diagnosing and monitoring time sensitive neurological disorders at the point of care in a manner otherwise not possible today," Dr Weinberger said.

Emvision was up half a cent or 0.7 percent to 73 cents.

MEMPHASYS

Memphasys said it has shipped the first batch of Felix sperm separation devices to key opinion leaders in Japan, India, Canada, Iran the US and China

Memphasys said the Felix device separated high quality sperm from semen, for use in human in-vitro fertilization, would be shipped with a total of six consoles and 320 cartridges by the end of December 2019.

The company said the majority of the sites receiving the first Felix devices were in countries believed to have a regulatory framework that matched Memphasys' objectives and timeframes, with New Zealand being in advanced discussions to secure an agreement, and devices to being sent to other sites by April 2020.

Memphasys said it planned for its staff to visit the sites in early January 2020, to assist with initial training and assessment activities, and had commenced the verification and validation process required to be completed before sales in the market could commence.

The company said it had filed a request with the Australian Therapeutic Goods Administration for a pre-submission meeting, ahead of a planned meeting with the TGA in early 2020 and planned commercial sales in mid to late 2020.

Memphasys was unchanged at five cents.

ANATARA LIFESCIENCES

Anatara says its pineapple-stem bromelain-derived product for human gastrointestinal disorders has indicated safety and enhancement of anti-inflammatory effect in mice.

Anatara chief executive officer Steven Lydeamore told Biotech Daily that the company had conducted a series of mouse trials that showed the gastrointestinal reprogramming, or Garp, supplement did not affect the uptake or potential activity when administered with probiotics and showed a synergy with anti-inflammation drugs.

Antara said the dietary supplement had been developed to specifically target inflammatory bowel disease and irritable bowel syndrome, and had the potential to reduce the dose of disease-modifying medications know to have negative side-effects.

In the media release, Mr Lydeamore said the data "adds to the strong scientific proof that our Garp dietary supplement has the potential to be game changing".

"Meeting this milestone keeps Anatara on track to an anticipated partnering deal by [the end of] 2020," Mr Lydeamore said.

Anatara was up four cents or 21.6 percent to 22.5 cents.

CANN GROUP, IDT AUSTRALIA

Cann Group and IDT say the first commercial medical marijuana product has been produced at Cann Group's Melbourne Southern cultivation facility and packed by IDT.

Cann Group and IDT said the cannabis dried flower was packed and labelled in 10gm bottles under current good manufacturing practice conditions and would undergo stability testing, before the first sales expected by April 2020.

The companies said this would allow a commercial launch to Australian patients in early 2020 under the special access scheme.

Cann Group was up five cents or 11.8 percent to 47.5 cents with 3.9 million shares traded.

IDT was up 1.5 cents or 12.5 percent to 13.5 cents.

CANN GLOBAL

Cann Global says it will establish a joint venture, Cann Global South Africa, with Koegas Medicinal Herbs to produce and distribute medical marijuana in Africa.
Cann Global said four strategic South African locations, including Wellington, Kuruman, Vryburg and Kokstad, would provide access to more than 1,500 acres with power and irrigation for greenhouse and broad acre growing.
The company said Koegas would hold 30 percent of the joint venture and it would issue Koegas 10 million Cann Global shares for its 70 percent.
Cann Global said Koegas would manage local personnel, logistics, government support and other resources, while Cann Global would provide technical, regulatory and operational expertise and access to Australian and global networks under the joint venture.
Cann Global was up 0.2 cents or 15.4 percent to 1.5 cents with 5.6 million shares traded.

PALLA PHARMA

Palla Pharma says it has negotiated more favorable terms for its debt facility with major shareholder Washington H Soul Pattinson.
Palla Pharma said it had reduced the interest rate from 11.2 percent to 8.25 percent, had extended the maturity date from August 2020 to August 2021 and had amended the facility limit from $31 million to $16 million.
Palla Pharma was untraded at $1.03.

CYCLOPHARM

Cyclopharm has requested a trading halt “pending the release of an announcement relating to a material capital raising”.
Trading will resume on December 23, 2019 or on an earlier announcement.
Cyclopharm last traded at $1.03.

CRESO PHARMA

Jamber Investments says it has increased its substantial shareholding in Creso from 8,000,000 shares (5.30%) to 20,369,753 shares (11.73%).
The Sydney-based Jamber, for the Amber Schwarz Family account, said it was allocated 5,825,250 settlement shares and acquired a further 6,544,503 shares in a placement for $1,250,000 or 19.1 cents a share on November 29, 2019 (BD: Nov 28, 2019).
Creso fell half a cent or four percent to 12 cents.

MGC PHARMACEUTICALS

MGC says the first shipment of its Cognicann for dementia and Alzheimer’s disease is en-route to Australia from Slovenia and will arrive in the coming days.
MGC said the shipment of the marijuana-based Cognicann from its Ljubljana Slovenia facility would allow it to commence the 50-patient phase IIb clinical trial of dementia and Alzheimer’s disease patients, in partnership with the Perth, Western Australia-based University of Notre Dame (BD: Jan 22, Nov 12, 2019).
The company said the trial would assess the best effectiveness and safety dose for symptoms associated with dementia and Alzheimer’s.
MGC was unchanged at 3.1 cents with 1.7 million shares traded.

THC GLOBAL GROUP

THC says it has appointed Angela Macquire as chief operating officer of THC Pharma, which operates its Southport, Queensland facility, effective from late January 2020.
THC said Ms Macquire had more than 30 years' experience in the pharmaceutical industry in Australia and the UK and held senior managerial and technical roles at PCI Clinical Services, Leo Pharma, IDT Australia, Glaxo Smith Kline and Pfizer.
THC fell half a cent or 1.3 percent to 37.5 cents.

BOD AUSTRALIA

Bod says alternate director Stephen Thompson has resigned "to pursue other opportunities".
Bod said that Mr Thompson was the alternative director to George Livery.
Bod fell half a cent or 1.6 percent to 30.5 cents.