Biotech Daily

Tuesday April 20, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AMPLIA UP 13%; PROTEOMICS DOWN 10%**

*** AUSTIN: MARIJUANA 'NO LOW BACK PAIN BENEFIT WITH OXYCODONE'**

*** GENIEUS 'DISCOVERS ALS BIOMARKER; POTENTIAL TREATMENT'**

*** EXOPHARM RAISES $12m**

*** AZURE RAISES $2.5m; NAME CHANGE TO VGI**

*** ELLUME: CVS STOCKS SARS-COV-2 RAPID TEST KIT**

*** KAZIA POTENTIAL $478m EVOTEC LICENCE FOR EVT801**

*** AMPLIA: FAK INHIBITORS REDUCE NASH FIBROSIS, IN MICE**

*** ANATARA: ETHICS APPROVAL FOR CSIRO 3FDC PSYCHOLOGY TRIAL**

*** ANALYTICA APPOINTS MARWA MIDDLE EAST INFUSION DISTRIBUTOR**

*** LITTLE GREEN APPOINTS BALANCIAL DANISH MARIJUANA DISTRIBUTOR**

*** HERAMED REQUESTS 'COMMERCIAL PARTNERSHIP' TRADING HALT**

*** OSPREY 111m CEO, DIRECTOR OPTIONS AGM**

*** AUSBIOTECH: PATRYS CEO DR JAMES CAMPBELL DIRECTOR**

*** RACE APPOINTS DR DAVID FULLER CMO**

*** KARST PEAK TAKES 9% OF PHARMAXIS**

MARKET REPORT

The Australian stock market fell 0.68 percent on Tuesday April 20, 2021, with the ASX200 down 47.8 points to 7,017.8 points. Nine of the Biotech Daily Top 40 stocks were up, 26 fell and five traded unchanged. All three Big Caps fell.

Amplia was the best, up three cents or 13.04 percent to 26 cents, with 788,129 shares traded. Medical Developments climbed 3.5 percent; Compumedics rose 2.2 percent; Paradigm and Universal Biosensors were up more than one percent; with Clinuvel, Nanosonics, Polynovo and Pro Medicus up by less than one percent.

Proteomics led the falls, down 13 cents or 9.6 percent to $1.22, with 96,202 shares traded, followed by Antisense down 9.5 percent to 19 cents, with 3.4 million shares traded. Impedimed and Next Science lost more than seven percent; Orthocell fell 6.5 percent; Imugene was down 5.1 percent; Actinogen fell 4.9 percent; Alterity, Cynata, Genetic Signatures, Immutep, Kazia, Prescient, Uscom and Volpara were down three percent or more; Cyclopharm, Mesoblast, Neuren, Pharmaxis and Telix shed two percent or more; Avita, Cochlear, CSL, Nova, Oncosil, Optiscan, Resmed and Starpharma were down more than one percent; with Opthea down by 0.7 percent.

AUSTIN HEALTH

Austin Health researchers say that a 100-patient, randomized, controlled trial of 400mg cannabidiol with oxycodone for back pain showed no difference to placebo.

A media release from the Medical Journal of Australia said that the researchers at Melbourne's Austin Health said that cannabidiol "does not reduce pain or hospital length of stay for people seeking help at a hospital emergency department for acute low back pain".

The Journal said the research, led by the Austin's Prof Anselm Wong and Dr Bronwyn Bebee was titled, 'The CANBACK trial: a randomised, controlled clinical trial of oral cannabidiol for people presenting to the emergency department with acute low back pain', was published in the Medical Journal of Australia and was available at: https://onlinelibrary.wiley.com/doi/10.5694/mja2.51014.

A media release from the Medical Journal of Australia said that cannabidiol did not have psychomotor or cognitive effects, and its safety profile was good.

The Journal said that cannabidiol had attracted increasing medical interest because of its anxiolytic, anti-inflammatory, anti-emetic, anti-epileptic, and anti-psychotic effects, and has been approved in several countries for the treatment of neuropathic pain. "Although CBD may be beneficial for reducing pain caused by inflammation, its utility for treating acute low back pain has not been assessed, until now," the Journal said.

The Journal said that patients presenting with acute, non-traumatic low back pain were randomized to receive 400mg cannabidiol or placebo in addition to standard emergency department analgesic medication, oxycodone.

The article said that mean pain scores at two hours were similar for the cannabidiol group (6.2 points) and the placebo group (5.8 points).

The median length of stay was 9.0 hours for the cannabidiol group and 8.5 hours for the placebo group, the Journal said.

The MJA said that oxycodone use during the four hours preceding and the four hours after receiving cannabidiol or placebo was similar for the two groups, as were reported side effects.

"We found no evidence of CBD used this way in patients with acute low back pain; the CBD and placebo groups did not differ with respect to hospital length of stay, adverse effects, and additional opioid medication use," the researchers said.

"Given its high cost, this is an important finding for patients who may consider requesting Therapeutic Goods Administration approval for access to CBD," the researchers said.

"With the gradual legalization of medicinal and recreational cannabis use in Australia and other countries, physicians must expect to see increasing numbers of patients taking cannabis products, whether prescribed by physicians or not," they wrote.

"It is imperative that the medical utility of CBD and other cannabis products, their side effects, and how these products interact with other medications be investigated in well-designed studies," the researchers said.

"[Our] trial was the largest clinical investigation of CBD for treating people with acute low back pain, one of the few to examine the effect of CBD without tetrahydro-cannabinol on acute pain, and was undertaken in a setting representative of clinical management of acute back pain in emergency departments," the researchers wrote.

"We found that CBD was not superior to placebo as an adjunct medication for treating low back pain in this setting," they concluded.

The Medical Journal of Australia said it was a publication of the Australian Medical Association.

GENIEUS

Genieus says that it has discovered a potential biomarker for amyotrophic lateral sclerosis, “paving the way [for] micro-RNA therapies”.
Genieus said that in a collaboration with Perth’s Perron Institute it was exploring the biomarker, a micro-RNA (miRNA) strand known as hsa-miR-30b-5p, as a target for amyotrophic lateral sclerosis (ALS) treatment, by developing an antisense oligonucleotide.
The company said it would use miRNA therapies “to explore ways of correcting disease-associated changes in gene expression”.
Genieus said it found that the biomarker, hsa-miR-30b-5p, was a common feature of ALS patients and the genetic expression of the microRNA, hsa-miR-30b-5p, was consistently upregulated in the spinal fluid of ALS patients.
The company said that research suggested the micro-RNA strand prevented the action of natural processes to maintain healthy neurons and the expectation was that by targeting hsa-miR-30b-5p, the progression of neurodegenerative diseases such as ALS could be significantly slowed or halted.
Genieus said it used “deep genomic analysis, using patient samples from spinal fluid via lumbar puncture, an area not typically sequenced for its genomic information”.
Genieus chair, and former Pharmaxis chief executive officer, Dr Alan Robertson said the company was “excited by this discovery and firmly believe that it represents a key step in understanding the very nature of the drivers of neurodegenerative disease”.
“Only once the biochemical drivers of disease are understood can we propose new treatment options for people with diseases such as ALS and Alzheimer’s disease,” Dr Robertson said.
Genieus is a private company.

EXOPHARM

Exopharm says it has “firm commitments” to raise $12 million in a placement at 72 cents a share to institutional and sophisticated investors.
Exopharm said the funds would accelerate its development activities, commercialization of its technology platforms and products, and support future partnerships and licences.
Exopharm said Canary Capital was the lead manager and Alto Capital was the broker to the placement, with a six percent fee on the funds raised.
Exopharm fell 11 cents or 12.0 percent to 81 cents with 1.9 million shares traded.

AZURE HEALTH TECHNOLOGY

Azure says its initial public offering for the National Stock Exchange has raised $2,497,000, with the VGI Group as a cornerstone investor having invested $2,250,000.
VGI chair Dr Vincent Lim Seng Peng said his company recognized that Azure had “biotechnology assets which have enormous value and scope for growth”.
Dr Lim said that the food additive products would “generate immediate revenues” and the two phase II-ready clinical development assets were expected to have efficacy data for non-alcoholic steato-hepatitis and pancreatic cancer in the next two years.
Azure said that “in recognition of the importance of the VGI Group becoming a substantial shareholder” it would trade as Azure Health Technology trading as VGI Health Technology and on listing on the National Stock Exchange next week, the ticker code would be VTL.
The company said it an extraordinary general meeting would vote to change the name to VGI Health Technology.
Azure is a public unlisted company.

ELLUME

Ellume says CVS Pharmacies will sell its 'Covid-19 Home Test' for the Sars-Cov-2 antigen in the US for $US38.99 ($A50.02) per test.

Ellume said that the Woonsocket, Rhode Island-based CVS was "America's leading retail pharmacy with nearly 10,000 locations".

The company said that CVS was the first retailer to carry the Ellume Home Test Kit for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and it would be available in select locations in Rhode Island and Massachusetts from April 19, "with increasing availability on CVS.com and in most CVS locations by the end of May".

CVS said the Ellume kit was "the first rapid, fully at-home test to receive emergency use authorization by the FDA for at-home use without a prescription".

"The test delivers results in 15 minutes through a free [application] downloaded to a smartphone, without the need for a second test," CVS said.

Ellume is a public unlisted company.

KAZIA THERAPEUTICS

Kazia says it will pay the Hamburg, Germany-based Evotec SE up to $477.9 million to licence its oral, small-molecule, oncology drug EVT801, originally invented by Sanofi.

Kazia said it would pay Evotec EUR1 million ($A1.5 million) and increments of up to EUR308 million ($A476.4 million) for clinical, regulatory, and commercial outcomes during the lifetime of the drug and a tiered single-digit royalty on the net sales.

The company said the licence allowed the development, manufacture, and commercialization of EVT801 in all territories and indications and the master services agreement was for collaboration on the development of EVT801.

Kazia said EVT801 was a small-molecule inhibitor of vascular endothelial growth factor receptor 3 (VEGFR3) and was expected to inhibit lymph-angio-genesis or the formation of new lymphatic cells around a growing tumor, with initial exploratory indications including kidney and liver cancer as well as soft tissue sarcoma.

Kazia said it expected to begin a phase I trial of EVT801 this year.

Kazia chief executive officer Dr James Garner said that "Evotec have done first-class work in the early development of EVT801, and the preclinical data package is exceptionally strong."

Kazia fell five cents or 3.3 percent to $1.48.

AMPLIA THERAPEUTICS

Amplia says its focal adhesion kinase (FAK) inhibitors, AMP886 and AMP945, have shown reduction of fibrosis from liver disease, in mice.

Amplia said the inhibitors were tested at Tokyo's SMC Laboratories and the model replicated progression from fatty liver to fibrotic liver and to liver cancer.

Last week, the company said it had dosed all participants in its 64-subject, phase I trial of AMP945 for cancer and fibrotic diseases (BD: Apr 15, 2021).

Today, Amplia said AMP945 delivered a "statistically significant reduction in liver fibrosis" in mice and both inhibitors showed a reduction of two activators of liver fibrosis, monoclonal antibody ER-TR7 and alpha-smooth muscle actin.

Amplia chief executive officer John Lambert said that it was "very encouraging to see such compelling data from using AMP886 and AMP945 in an industry recognized model of [non-alcoholic steato-hepatitis]."

Amplia was up three cents or 13.04 percent to 26 cents with 788,129 shares traded.

ANATARA LIFESCIENCES

Anatara says it has ethics approval for a 100-participant trial of its 3FDC dietary supplementation on adult psychological functioning.

Anatara said the randomized, double-blinded and placebo-controlled trial would evaluate the safety and efficacy of 3FDC in adults with moderate anxiety, stress or depression.

The company said the study would be conducted by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) at its Adelaide-based Nutrition and Health research clinic.

Anatara said 3FDC was a component of its pineapple stem, bromelain-based gastro-intestinal reprogramming (Garp) food supplement and was targeted to release at the junction between the small and large intestine to affect the large intestine microbiome, and participants would receive either 3FDC or placebo, twice a day for six weeks.

Anatara said CSIRO would develop guidelines and recruit the participants from July, with participants assessed at the start and end of the period.

Anatara chief executive officer Steve Lydeamore said that it was “gratifying that [our] focus on gut health and integrity has allowed us to capitalize on our research in [irritable bowel syndrome] with the potential to address other microbiome centric conditions”.

“The current study has the potential, not only to help those suffering mood disorders, but to significantly add to our understanding of Garp in non-[irritable bowel syndrome] participants,” Mr Lydeamore said.

Anatara fell half a cent or 2.7 percent to 18 cents.

ANALYTICA

Analytica says it has a 10-year agreement with Marwa’s Office for Export and Import Medical Supplies for its enhanced infusion system.

Analytica said the Tanta, Egypt-based Marwa would distribute and market its enhanced infusion system in Egypt, Bahrain, Iran, Iraq, Jordan, Kuwait, Lebanon, Saudi Arabia and United Arab Emirates.

The company said its enhanced infusion system contained a supplemental float system that restarted intravenous fluid infusion after medication delivery.

Analytica said it would receive 10 percent of gross sales from the commencement to 12 months, 12.5 percent for the year after and 15 percent thereafter.

The company said it would retain the ownership of EIS intellectual property, continue its development and sell outside the licenced territory.

Analytica was up 0.1 cents or 25 percent to 0.5 cents with 5.4 million shares traded.

LITTLE GREEN PHARMA

Little Green says it has appointed Copenhagen’s Balancial Danmark ApS distributor of its medical marijuana oil and flower products.

Little Green said the non-exclusive, fixed price, five-year, distribution agreement was conditional on approvals to export its products into Denmark.

The company said the agreement required Balancial to buy at least 20,000 units before it could manufacture or supply any products similar to its products.

Little Green said that there was no minimum purchase order but each order must be for at least 2,000 units and Balancial was required to pre-pay 100 percent of the first shipment prior to delivery and pre-pay 50 percent of following confirmed orders.

Little Green was up two cents or 2.6 percent to 78.5 cents.

HERAMED

Heramed has requested a trading halt pending an announcement “regarding a commercial partnership agreement”.
Trading will resume on April 22, 2021 or on an earlier announcement.
Heramed last traded at 12 cents.

OSPREY MEDICAL

Osprey says its annual general meeting will vote to issue 110.8 million options to chief executive officer Michael McCormick and three directors.
Osprey said it proposed to issue chief executive officer Michael McCormick 100,000,000 options over Chess depository instruments (CDIs), chair John Erb, 6,000,000 options, and directors Neville Mitchell 2,800,000 options and Sandra Lesenfants 2,000,000 options.
The company said it would issue 50 percent of the options to Mr McCormick following the meeting and the remainder in February 2022, exercisable at the closing price on issue.
Osprey said 30 percent of Mr McCormick’s options would be vested if the company had a positive cashflow in any three-month period from July 1, 2021 to June 30, 2024 and the remaining 70 percent had no performance hurdles, other than time-based vesting.
The company said that half of the directors’ options would be issued after the meeting and the remainder in February 2022, exercisable at the closing price on the date of issue within 10 years, with no performance hurdles and 25 percent vesting one year from the date of issue and the remainder vesting in monthly instalments over three years.
Osprey said the meeting would vote to re-elect director Dr Chris Nave, approve the 10 percent placement capacity and approve the amendment of its 2016 stock incentive plan to increase the number of shares of common stock issuance.
The online meeting will be held on May 11, 2021 at 10am (AEST).
Osprey was unchanged at 1.8 cents with 3.2 million shares traded.

AUSBIOTECH

Ausbiotech says it has appointed Patrys chief executive officer Dr James Campbell as a director, contributing commercialization and capital-raising expertise to the board.
Ausbiotech said that Dr Campbell had more than 25 years’ experience in research, research management, consulting and venture capital.
The industry organization said that Dr Campbell previously worked as a researcher for the Commonwealth Scientific and Industrial Research Organisation and was appointed to the investment committee of Uniseed.
Ausbiotech said that Dr Campbell was Chemgenex chief operating officer and co-founded Gemini Biotechnology, advising life science companies on fundraising, mergers and acquisitions, partnering and corporate strategy.
The industry organization said that Dr Campbell was a director of Prescient and was the author of more than 15 peer-reviewed papers ranging from plant biochemistry to bio-informatics and antibody development, and was an inventor of Patrys antibody candidate PAT-DX1.
Ausbiotech said that Dr Campbell held a Bachelor of Science from the University Melbourne, a Master of Business Administration from the Melbourne Business School and a Doctor of Philosophy from Deakin University.

RACE ONCOLOGY

Race says it has appointed Dr David Fuller as its full-time chief medical officer, effective from July 1, 2021.

Race said that Phillip Lynch would continue as managing-director and Dr Daniel Tillett as chief scientific officer.

The company said that Dr Fuller had “a deep understanding of the successful development and commercialization of novel pharmaceuticals: with 30 years of research and development experience, including pre-clinical and clinical development, medical and regulatory affairs and commercialization.

Race said that Dr Fuller was currently Syneos Health head of oncology clinical development, chair of Epiaxis Therapeutics and a non-executive director of Adalta.

The company said that previously Dr Fuller was a director at Linear Clinical Research, chair of Dimerix Bioscience, and an executive at Trident Clinical Research, Arana Therapeutics and Genzyme Europe.

Race said that Dr Fuller led major market drug approvals including Moraxen, Busulfex, Xyrem and Renagel, and had designed phase I, II and III studies for orphan and non-orphan drugs.

The company said that Dr Fuller held a Bachelor of Medicine and Bachelor of Surgery, and a Bachelor of Pharmacy from the University of Sydney.

Race was up five cents or 1.5 percent to $3.29 with 525,384 shares traded.

PHARMAXIS

Karst Peak Capital says it has become a substantial shareholder in Pharmaxis with 40,214,643 shares or 8.90 percent of the company.

The Hong Kong-based Karst Peak said that on April 16, 2021, it bought 40,214,643 shares for $3,217,171 or eight cents a share.

Pharmaxis fell 0.2 cents or 2.4 percent to 8.2 cents with 1.15 million shares traded.