



Biotech Daily

Tuesday September 8, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMMUTEP UP 14%; OSPREY DOWN 4%**
- * **OPYL PICKS COVID-19 VACCINE WINNERS**
- * **AMPLIA PHASE I AMP945 CANCER TRIAL APPROVED**
- * **EMVISION PILOT STROKE IMAGING STUDY ENROLLED**
- * **RECCE: '327, 529 REDUCE SARS-COV-2, IN-VITRO'**
- * **BOTANIX: BTX1801 'ELIMINATES MRSA EX-VIVO, IN-VITRO'**
- * **NOXOPHARM HIRES PARAXEL FOR VEYONDA PROSTATE CANCER TRIAL**
- * **PYC COMBINES CPP, LIPID NANOPARTICLES FOR DRUG DELIVERY**
- * **ZELIRA SUBSIDIARY FOR MARIJUANA TOOTHPASTE**
- * **SUDA: AUSTRALIAN PATENT FOR ANAGRELIDE FOR CANCER**
- * **US PATENT FOR ANTERIS (ADMEDUS) ADAPT TISSUE PROCESS**
- * **OPTISCAN PLEADS SCHULTZ TO ASX 35% PRICE QUERY**
- * **MGC REQUESTS 'FINANCING FACILITY' TRADING HALT**

MARKET REPORT

The Australian stock market was up 1.06 percent on Tuesday September 8, 2020, with the ASX200 up 63.0 points to 6,007.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and two were untraded. All three Big Caps rose.

Immutep was the best, up 2.5 cents or 13.9 percent to 20.5 cents, with 9.95 million shares traded. Optiscan climbed a further 12.4 percent; Amplia improved 7.7 percent; Oncosil, Prescient and Universal Biosensors were up more than three percent; Clinuvel, CSL, Pro Medicus, Telix and Volpara rose more than two percent; Antisense, Avita and Compumedics were up more than one percent, with Cochlear, Genetic Signatures, Mesoblast, Nanosonics, Next Science and Resmed up by less than one percent.

Osprey led the falls, down 0.1 cents or 4.2 percent to 2.3 cents, with 9.5 million shares traded. Cynata, LBT and Starpharma lost more than three percent; Medical Developments and Orthocell shed more than two percent; Neuren, Paradigm and Pharmaxis were down more than one percent; with Kazia, Opthea and Polynovo down by less than one percent.

[OPYL AI](#)

Opyl has named the three leading severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) vaccine candidates by its artificial intelligence program.

Last week, Opyl said a study using its artificial intelligence clinical trial prediction software had analyzed the probability of Covid-19 vaccine and antibody therapy trial success, but did not name any companies, citing 'confidentiality' (BD: Sep 3, 2020).

Yesterday, in a six-page response to ASX queries, Opyl said the Covid-19 model was not proof-of-concept, as described on September 3, but rather "the model's first major use case" (BD: Sep 7, 2020).

Today, following publication in a national newspaper, Opyl chief executive Michelle Gallaher told Biotech Daily that her company had developed a list of the 10 companies most likely to develop a Covid-19 vaccine.

Ms Gallaher said the artificial intelligence software had selected the US National Institute of Allergy and Infectious Diseases-funded Moderna Inc mRNA1273 vaccine as the leading contender, followed by the Pfizer and Biontech collaboration, with the Oxford University-Astrazeneca proposed vaccine third in the list.

Ms Gallaher said the list of 10 did not include the University of Queensland-CSL candidate nor the Russian Gamaleya Research Institute Sputnik V.

The US publication Endpoints News currently lists Pfizer, Moderna and Astrazenca as the top three contenders, in that order, with Sputnik V at sixth and the University of Queensland-CSL candidate at number 23 of 28.

Opyl fell 2.5 cents or 11.4 percent to 19.5 cents with 2.5 million shares traded.

[AMPLIA THERAPEUTICS \(FORMERLY INNATE IMMUNOTHERAPEUTICS\)](#)

Amplia says Melbourne's Alfred Hospital has approved a 64-patient, phase I safety trial of its focal adhesion kinase inhibitor AMP945 in healthy volunteers.

In 2018, Innate acquired Amplia Therapeutics for its FAK cancer program, including both AMP886 and AMP945, for 18.5 million shares, worth about \$1.3 million and later changed its name to Amplia (BD: Mar 23, Sep 5, 2018).

Today, Amplia said the double blind, placebo-controlled trial would establish the safety profile of oral doses of AMP945 and would assess the pharmaco-dynamics and pharmaco-kinetics of the drug.

The company said it would include an initial single ascending dose study, followed by a multiple ascending dose study, with the first patient expected to be dosed by early October and single ascending dosing expected to be completed by the end of the year.

Amplia said data from the trial was expected by July 2021 and would be used to support phase II clinical trials for specific, hard-to-treat cancers and fibrotic diseases.

Amplia was up one cent or 7.7 percent to 14 cents with 2.4 million shares traded.

[EMVISION MEDICAL DEVICES](#)

Emvision says it completed enrolment of its 30-patient, pilot clinical study of its portable imaging technology for ischaemic or haemorrhagic stroke patients.

Emvision said it expected top-line results by the end of the year.

Emvision was up 10 cents or 4.3 percent to \$2.45.

RECCE PHARMACEUTICALS

Recce says Recce-327 and Recce-529 shown concentration-dependent reductions in severe acute respiratory syndrome-coronavirus-2 (Sars-Cov-2), in-vitro.

Recce said the studies, undertaken by the North Carolina-based Path Bioanalytics and the University of Tennessee's Health Science Centre, used organoids made from human airway epithelial cells infected with Sars-Cov-2, the virus that caused Covid-19.

The company said the concentrations used were "far lower" than those used in pre-clinical data of Recce-327 through intravenous infusion.

Recce said that in a related study, the concentrations of both compounds indicated an "excellent toxicity profile" of a less than 0.25 percent effect on Vero monkey cells.

The company said that based on these results, it would advance to in-vivo Covid-19 studies of both compounds in ferrets, using intra-nasal administration.

Recce said it expected the US ferret study to begin this month and be completed by the end of the year.

The company said further testing would need to be completed before either compound could be deemed safe or effective for Sars-Cov-2.

Recce chairman Dr John Prendergast said the company was "very pleased with the anti-viral activity against Sars-Cov-2 demonstrated by our two compounds, Recce-327 and Recce-529 in vitro, and look forward to further success in the forthcoming ferret model studies".

"As Covid-19 infections and mortalities continue to rise, an effective treatment is critical," Dr Prendergast said.

"Recce's anti-infective technology is striving to address the global health problem of emerging viral pathogens," Dr Prendergast said.

Recce was up 15 cents or 10.2 percent to \$1.625 with 1.8 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says pre-clinical studies show that synthetic cannabinoid BTX1801 "eliminates methicillin-resistant Staphylococcus aureus" and prevents bacterial growth.

In March, Botanix said it expected to start a 60-patient, phase IIa, double-blind, controlled trial of BTX1801 for surgical site infections by July (BD: Mar 13, Aug 12, 2020).

Today, the company said it had new data from an ex-vivo efficacy study, which showed that BTX1801 eliminated MRSA from infected human skin explants, from patients undergoing abdominoplasty, after 24 hours of treatment in a dose-dependent manner.

Botanix said treatment with cannabidiol in all concentrations at 24 hours resulted in significant reductions ($p < 0.05$) from the control samples.

The company said there was no evidence of a reduction in viability for any cannabidiol concentrations compared to the control.

Botanix said a second study assessed the mechanism of action of synthetic cannabidiol on methicillin-resistant Staphylococcus aureus (golden staph or MRSA) and showed that it disrupted the bacterial membrane, resulting in cell death and prevented bacterial growth.

Botanix executive chairman Vince Ippolito said the company was "extremely encouraged by this new human explant data for BTX1801".

"The results show rapid bactericidal activity of BTX1801 against MRSA and that the ointment completely eradicates MRSA from clinically relevant human skin explants after 24 hours," Mr Ippolito said.

The company said this new data supported the phase IIa study, which targeted completion by the end of 2020.

Botanix was up 0.2 cents or 3.7 percent to 5.6 cents with 13.4 million shares traded.

NOXOPHARM

Noxopharm says it has appointed Paraxel Biotech as the clinical research organization for its up-to 200-patient, phase II study of Veyonda for prostate cancer.

Noxopharm said the direct and abscopal response to radiotherapy 2 (Daart-2) study was a multi-national, control-arm study of Veyonda or NOX66 with radiotherapy for men with end-stage metastatic castrate-resistant prostate cancer.

The company said the Waltham, Massachusetts-based Paraxel would start hospital and clinician recruitment, with patient recruitment expected to commence in early 2021.

Noxopharm fell two cents or 6.35 percent to 29.5 cents.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says embedding its cell penetrating peptides in the surface of lipid nanoparticles improves the efficacy of lipid nanoparticle drug delivery, in-vitro.

PYC said that combining its peptides, formerly known as 'Phylomers', with lipid nanoparticles "creates a potent and safe delivery technology to carry [small interfering ribonucleic acid] siRNA into cells".

The company said there was no observed toxicity, which demonstrated a potential path for non-viral DNA and RNA drug delivery.

PYC said the next step would be to demonstrate the utility of the cell penetrating peptides and lipid nanoparticles combinations in animals.

PYC was unchanged at 12.5 cents with 4.5 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has partnered with Sprinjene and formed an oral care products subsidiary to commercialize hemp-derived, marijuana-based oral care products.

Zelira said Health and Natural Beauty USA Corp would manufacture the products, including its first over-the-counter product, a cannabinoid toothpaste formulation developed by Sprinjene chief executive officer and founder Dr Sayed Ibrahim.

The company said it expected to begin commercialization activities in retail and other channels in the US by January 2021 and was on-track to launch five new products in 2020.

Zelira said that the Piscataway, New Jersey-based Sprinjene gluten-free, cruelty-free, vegan, kosher and halal oral care products were manufactured by Health and Natural Beauty USA Corp, which was located at the same address as Sprinjene.

Zelira fell 0.1 cents or 1.7 percent to 5.7 cents with 4.5 million shares traded.

SUDA PHARMACEUTICALS

Suda says the Australian Patent Office will grant a patent relating to its anagrelide for metastatic disease in patients with solid tumor cancers.

Suda said the patent, titled 'Prevention and Treatment of Metastatic Disease in Thrombocytotic Cancer Patients' would protect its intellectual property until December 2035.

The company said it held a granted patent for Europe and earlier this year received a grant for the patent in Japan.

Suda was up half a cent or 11.6 percent to 4.8 cents with 7.1 million shares traded.

[ANTERIS TECHNOLOGIES \(FORMERLY ADMEDUS\)](#)

Anteris says the US Patent and Trademark Office has granted a patent for the sterilization method used in the manufacture of its Adapt tissue.

The USPTO website said that the patent, titled 'Sterilisation process', was filed on May 9, 2016, and it named the Perth, Western Australia-based William Morris Leonard Neethling as the inventor.

The USPTO said that "the present invention relates to a process for sterilizing implantable biomaterials".

"In particular, the invention relates to a process for sterilizing collagen-containing implantable biomaterials and storage thereafter".

Anteris was up two cents or 0.5 percent to \$4.02.

[OPTISCAN IMAGING](#)

Optiscan has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 34.8 percent from 8.9 cents yesterday September 7, 2020 to 12.0 cents today, September 8, but did not note an increase in the trading volume.

Optiscan was up 1.1 cents or 12.4 percent to 10 cents with 9.95 million shares traded.

[MGC PHARMACEUTICALS](#)

MGC has requested a trading halt "pending the release of an announcement by the company in relation to a material new financing facility".

Trading will resume on September 10, 2020 or on an earlier announcement.

MGC last traded at 2.4 cents.