



Biotech Daily

Wednesday June 2, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: AMPLIA UP 37%; OPTISCAN DOWN 11%**
- * **TRAJAN TO LIST ON ASX ON MONDAY; 300+ STAFF INVESTORS**
- * **AMPLIA: AMP945 IMPROVES PANCREATIC CANCER CHEMO, IN MICE**
- * **ONCOSIL WITHDRAWS TGA APPLICATION ON DATA**
- * **RACE APPOINTS PAREXEL FOR PHASE I/II BISANTRENE AML TRIAL**
- * **INVION, RMW CHO \$4.5m PLACEMENT, PHOTOSOFT DEAL**
- * **ACTINOGEN: PART-A XANAMIA XANAMEM COGNITION TRIAL APPROVED**
- * **PHARMAUST PHASE I MONEPANTEL MND TRIAL APPROVED**
- * **EUROPEAN PATENT FOR IMMUTEP CANCER COMBINATIONS**
- * **REGAL BELOW 5% OF GENETIC SIGNATURES**
- * **CRYOSITE DIRECTOR ANDREW KROGER TAKES 42%**
- * **MERCER STREET TAKES 5.5% OF ANTERIS**
- * **OPTHEA: PROF JULIA HALLER, JUDITH ROBERTSON DIRECTORS**
- * **AVITA APPOINTS JAMES CORBETT, JAN STERN REED DIRECTORS**

MARKET REPORT

The Australian stock market fell 0.27 percent on Wednesday June 2, 2021, with the ASX200 down 19.0 points to 7,142.6 points. Ten of the Biotech Daily Top 40 stocks were up, 25 fell and five traded unchanged. All three Big Caps fell.

Amplia was the best, up 7.5 cents or 36.6 percent to 28 cents with 8.4 million shares traded. Prescient climbed 30 percent on no news; Actinogen was up 23.8 percent; Osprey rose 6.25 percent; Compumedics and Imugene were up more than five percent; Cynata rose 3.6 percent; Cyclopharm was up 1.5 percent; with Next Science and Pro Medicus up by less than one percent.

Optiscan led the falls, down four cents or 11.1 percent to 32 cents, with 761,960 shares traded. Oncosil lost 7.6 percent; Uscom was down 5.6 percent; Impedimed and Universal Biosensors fell four percent or more; Kazia, Nanosonics, Neuren and Patrys were down more than three percent; Antisense, Avita, LBT, Opthea, Proteomics, Resonance and Volpara shed two percent or more; Medical Developments, Pharmaxis, Polynovo, Resmed, Starpharma and Telix were down more than one percent; with Clinuvel, Cochlear, CSL, Immutep, Orthocell and Paradigm down by less than one percent.

TRAJAN SCIENTIFIC AND MEDICAL

Trajan says that following its \$90 million initial public offer, adding more than 300 staff investors, it expects to list on the ASX under the code TJN on Monday June 7, 2021. Trajan said that as well as raising funds from external investors, it undertook an 'employee gift offer' and option plan "to recognize and reward the contribution of staff", but some staff were not eligible due to their country of residence.

In April, Trajan founder and chief executive officer Stephen Tomisich told Biotech Daily that the company was headquartered in Ringwood, Melbourne, with 450 staff in offices in Australia, the US, England, Japan and Malaysia (BD: Apr 19, 2021).

Mr Tomisich said at that time the company was profitable and had revenue of about \$80 million in the last financial year.

Today, the company said that "demand for shares significantly exceeded the size of the offer", with strong participation from funds in Australia, Asia, the UK, and New Zealand". "Sharing the Trajan story with the investment community in recent months has been exhilarating," Mr Tomisich said. "The response is a strong validation of the substance and strength of the Trajan business today and its prospects for tomorrow."

Trajan said it had four dedicated precision manufacturing facilities in Australia, Malaysia, and US, and was a "developer and manufacturer of analytical science instruments, devices, and solutions used in biological, food and environmental analysis".

The company said its products were used across the analytical workflow and had broad life science applications including pharmaceutical, clinical diagnostics and pathology.

Trajan said that its customers and partners were included original equipment manufacturers, pharmaceutical companies and contract research organizations.

The company said that the offer, other than the employee gift offer, under which no proceeds would be raised, was fully underwritten by joint lead managers, Canaccord Genuity (Australia) and Ord Minnett, with Ernst and Young acting as financial adviser and DLA Piper providing legal advice.

Trajan is currently a public unlisted company.

AMPLIA THERAPEUTICS

Amplia says its focal adhesion kinase (FAK) inhibitor AMP945 improves the anti-cancer activity of gemcitabine and paclitaxel by 27 percent for pancreatic cancer, in mice.

In April, Amplia said mouse studies showed that AMP945 enhanced chemotherapy and impacted pancreatic cancer biomarkers (BD: Apr 28, 2021).

Today, the company said that data from work with Prof Paul Timpson of Sydney's Garvan Institute of Medical Research, showed that AMP945 improved the anti-cancer activity of the first-line treatment of combined gemcitabine (Gemzar) and paclitaxel (Abraxane).

Amplia said the data showed that adding intermittent doses of its AMP945 to the standard-of-care therapy increased survival by 27 percent.

Prof Timpson said "the pancreatic cancer cells used in this experiment are extremely aggressive, so showing any beneficial effect on survival is very encouraging".

"A 25 percent improvement in survival in this model is very impressive and a level of improvement that we rarely see," Prof Timpson said.

Amplia chief executive officer Dr John Lambert said that the data "further underpin the rationale for our planned phase II clinical trial in pancreatic cancer".

"Earlier data told us that adding AMP945 to gemcitabine and Abraxane increased cancer cell death and reduced proliferation, and this new data tells us that those effects actually translate into prolonged survival in this model," Dr Lambert said.

Amplia climbed 7.5 cents or 36.6 percent to 28 cents with 8.4 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has withdrawn its Therapeutic Goods Administration application on the basis that further data comparing its device with standard therapies is expected.

Oncosil said that “following the submission to the TGA for inclusion onto the Australian Register of Therapeutic Goods, the company has decided to withdraw the application on the basis that the provision of additional clinical data comparing the performance of the Oncosil device [for pancreatic cancer] directly with other standard therapies is expected to support the application”.

Oncosil chief executive officer Nigel Lange said the company appreciated “the ongoing dialogue with the TGA as part of our application process”.

“Following the feedback we received from the TGA, there is the opportunity for us to submit a strengthened application at a later date, with the inclusion of comparative clinical data,” Mr Lange said.

“While Australia is a strategic market in the future, we remain focused on the European and US markets, where our long-term and material growth opportunities lie,” Mr Lange said.

Oncosil fell 0.6 cents or 7.6 percent to 7.3 cents with 3.85 million shares traded.

RACE ONCOLOGY

Race says it has appointed Parexel as its contract research organization for its 60-patient, phase I/II trial of Bisantrene for extramedullary acute myeloid leukemia.

Race said the open label trial would be led by principal investigator Prof Anoop Enjeti, the director of haematology at the Waratah, New South Wales Calvary Mater Newcastle and John Hunter Hospitals.

The company said it would pay the Durham, North Carolina-based Paraxel International an initial fee of \$1.1 million and additional payments would be made on reaching milestones.

Race said it expected the trial to be completed in 36 to 40 months with full patient recruitment to be completed in about 18 months.

The company said the trial would be conducted at 10 sites in Australia in a two-stratum design, with the first stratum consisting of up to 30 patients and the second stratum for dose escalation between four and 10 patients and up to 30 patients in the expansion phase.

Race said in the first stratum it would use Bisantrene as a high dose, single agent treatment over seven days in patients with capability to tolerate high intensity chemotherapy, followed by one or more cycles of consolidation treatment of Bisantrene with azacitidine, a standard of care drug.

The company said in the second stratum, Bisantrene would be used as a low dose fat mass and obesity associated (FTO) targeted agent in combination with the oral hypomethylating agent, Inqovi (decitabine and cedazuridine) for patients unable to tolerate high intensity chemotherapy.

Race said the primary endpoint for both strata would be complete response and complete response with incomplete haematological recovery which would aim to bridge to an allogeneic haematopoietic stem cell transplant.

The company said the secondary endpoint would include safety and tolerability of Bisantrene, overall and event-free survival, and the level of FTO expression with response to treatment.

Race chief scientific officer Dr Daniel Tillett said the trial would be “transformational”.

Race fell three cents or 0.8 percent to \$3.55 with 935,168 shares traded.

INVION

Invion says RMW Cho Health will provide \$4.5 million in a placement at 1.4 cents a share to co-develop its Photosoft technology for atherosclerosis and infections.

Invion said it had a co-development, exclusive and licence agreement with RMW for the Photosoft technology and it would contribute a one-time payment of \$2.25 million for the existing intellectual property and as developmental costs.

The company said the Photosoft technology used non-toxic photo-sensitizers and visible light combined with oxygen to produce cytotoxic-reactive oxygen that killed malignant cells, shut down tumors and stimulated the immune system.

Invion said it would have exclusive distribution rights to the Photosoft technology in the Asia Pacific region for atherosclerosis and infectious diseases including viral, bacterial, fungal and parasitic infections.

The company said the Asia Pacific "includes Asia and Oceania, other than Australia and New Zealand, which are the subject of an existing distribution and licence agreement with RMW, and excludes [the] Middle East, Russia and the specified territories of China, Hong Kong, Macau and Taiwan.

Invion fell 0.4 cents or 20 percent to 1.6 cents with 98.3 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it has ethics approval for its 100-healthy older volunteer, part-A Xanamia dosing study of Xanamem for cognition.

Actinogen said the Bellberry Human Research Ethics Committee approved the enrolment of patients expected to begin next month.

The company said part-A would be a dose-ranging study with Xanamem doses of 5mg and 10mg, at four clinics in Australia enrolling volunteers aged 50 years and above, to confirm the minimum effective dose.

Actinogen said the part-B study would assess the efficacy of the minimum dose and would be conducted with patients with mild cognitive impairment, due to biomarker-positive, early-stage Alzheimer's disease.

Actinogen was up 2.5 cents or 23.8 percent to 13 cents with 28.3 million shares traded.

PHARMAUST

Pharmaust says it has ethics approval for a 12-subject, phase I trial to assess monepantel in patients with amyotrophic lateral sclerosis or motor neuron disease.

Pharmaust said Fight MND would provide \$881,085 for the trial and it would be conducted in collaboration with Fight MND, Melbourne's Calvary Healthcare Bethlehem and the Sydney-based Macquarie University.

In May, the company said it appointed Dr Kim Agnew as the principal investigator of its second trial of monepantel for dogs with naïve B cell lymphoma (BD: May 14, 2021).

Today, Pharmaust said study would test the safety of monepantel in motor neurone disease, with each level of dose escalation lasting 28 days.

The company did not state the doses to be trialed, but the trial listing on clinicaltrials.gov said that one of the primary outcomes was selecting the dose for a phase II trial.

Pharmaust said it expected monepantel to receive US Food and Drug Administration orphan drug designation for motor neurone disease.

Pharmaust was up 0.3 cents or 3.3 percent to 9.5 cents.

IMMUTEP

Immutep says that the European Patent Office has granted a patent covering its combination of IMP321 with a programmed death 1 (PD-1) or ligand (PD-L1) inhibitor. Immutep said that the patent, titled 'Combined Preparations for the Treatment of Cancer', would protect its intellectual property until January 8, 2036.

The company said the patent covered the related methods of use of eftilagimod alpha or IMP321 with the inhibitors for cancer.

Immutep fell half a cent or 0.7 percent to 69.5 cents with four million shares traded.

GENETIC SIGNATURES

Regal Funds Management says it has ceased its substantial holding in Genetic Signatures.

The Sydney-based Regal Funds said between April 27 and May 28, 2021 it sold shares, with the single largest sale 700,000 shares for \$959,000 or \$1.37 a share.

Genetic Signatures was unchanged at \$1.16.

CRYOSITE

Cryosite director Andrew John Kroger says he has increased his substantial shareholding from 18,889,612 shares (40.31%) to 19,710,506 shares (42.06%).

The London-based Mr Kroger said that on June 1, 2021, he acquired 820,894 shares on market at 36 cents a share.

Cryosite was untraded at 35 cents.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

New York's Mercer Street Global Opportunity Fund says it has become a substantial share-holder in Anteris with 383,367 shares or 5.52 percent.

Mercer Street said that on April 13, it acquired 55,383 shares for \$550,000 or \$9.93 a share as part of a drawdown facility and on May 31, 2021 acquired a further 66,667 shares for \$500,000 or \$7.50 a share (BD: Jan 17, Apr 12, 15, 2021).

Anteris was unchanged at \$7.98.

OPTHEA

Opthea says it has appointed Prof Julia Haller and Judith Robertson as non-executive directors, effective from June 1, 2021.

Opthea said Prof Haller was an ophthalmologist and vitreoretinal surgeon, previously was a professor of ophthalmology at the Baltimore, Maryland-based Johns Hopkins University and had published more than 350 scientific articles and book chapters.

The company said that Prof Haller held a Bachelor of Arts from New Jersey's Princeton University and a Doctor of Medicine from Boston's Harvard Medical School.

Opthea said that Ms Robertson was most recently Eleusis chief commercial officer and prior to that held the same role at Aerie Pharmaceuticals.

The company said Ms Robertson was the head of immunology and ophthalmology at Johnson & Johnson and head of ophthalmology at Novartis.

Opthea said that Ms Robertson held a Bachelor of Arts from Toronto's Ryerson University and a Master of Business Administration from Chicago's Northwestern University.

Opthea fell 3.5 cents or 2.3 percent to \$1.495.

AVITA MEDICAL

Avita says it has appointed James Corbett and Jan Stern Reed as directors, effective from July 1, 2021.

Avita said that Mr. Corbett has 40 years' experience in medical devices and previously was the chief executive officer of Microtherapeutics Inc, EV3 Inc Alphatec Spine, Home Diagnostics Inc and Vertos Medical.

The company said Mr Corbett had capital market and governance experience.

Avita said that Mr Corbett held a Bachelor of Science in Business Administration from the Lawrence-based University of Kansas.

The company said that Ms Reed had more than 35 years of legal, management and business experience in the healthcare industry and was previously the general counsel and corporate secretary at Walgreens Boots Alliance, the Solo Cup Company's general counsel, corporate secretary and head of human resources, and Baxter International's general counsel, corporate secretary.

Avita said that Ms Reed was a director of Stepan Co and Angiodynamics Inc.

The company says Ms Reed held a Bachelor of Arts from the Ann Arbor-based University of Michigan, and a Doctor of Jurisprudence from Chicago's Northwestern University.

Avita fell nine cents or two percent to \$4.50.