Biotech Daily

Thursday August 5, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NEUREN UP 6%; ALTERITY DOWN 8%**

*** INVION REVENUE DOWN 33% TO $2.3m, LOSS UP 56% TO $1.5m**

*** 4D, UNNAMED US PARTNERS WORK ON PULMONARY INTERVENTION**

*** NEUREN: ACADIA ENROLS PHASE III TROFINETIDE FOR RETT SYNDROME**

*** TELIX: 1st PATIENT DOSED IN CUPID TLX592 PROSTATE CANCER TRIAL**

*** IMMUTEP DOSES 1st TRIPLE COMBINATION INSIGHT-003 PATIENT**

*** IMUGENE, CELULARITY COMBINE THERAPIES FOR SOLID TUMORS**

*** DORSAVI EXTENDS MEDTRONIC DEAL, WORTH $231k**

*** PHARMAXIS: PXS-5505, CHEMO IMPROVES LIVER CANCER, IN MICE**

*** NOXOPHARM: 'VEYONDA ENHANCES 177-LUTETIUM-PSMA-617, IN MICE'**

*** EMYRIA $491k UWA MDMA FOR NEUROLOGY CONTRACT**

*** ALTERITY: US PATENT FOR IRON IN NEURO-DEGENERATIVE DISEASES**

MARKET REPORT

The Australian stock market was up 0.11 percent on Thursday August 5, 2021, with the ASX200 up 7.9 points to 7,511.1 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell and eight traded unchanged.

Neuren was the best, up 10 cents or 6.25 percent to $1.70, with 390,102 shares traded. Resonance rose 3.7 percent; Actinogen, Amplia, Immutep and Patrys improved two percent or more; Impedimed, Medical Developments, Next Science, Pharmaxis and Resmed were up one percent or more; with CSL, Genetic Signatures and Starpharma up by less than one percent.

Yesterday's 12.1 percent best, Alterity, led the falls, down 0.3 cents or 8.1 percent to 3.4 cents, with 13.05 million shares traded. Osprey lost 7.1 percent; LBT and Optiscan fell more than four percent; Compumedics, Imugene, Mesoblast and Paradigm were down more than three percent; Prescient and Volpara shed more than two percent; Avita, Clinuvel, Nanosonics, Polynovo and Universal Biosensors were down by more than one percent; with Cochlear, Kazia, Opthea, Pro Medicus, Proteomics and Telix down by less than one percent.

INVION

Invion says revenue for the year to June 30, 2021 was down 33.0 percent to $2,330,027 with net loss after tax up 55.5 percent to $1,482,951.
Invion said revenue was from the Hong Kong-based Cho Group under their research and development services agreement for the Photosoft light therapy for cancer licence.
The company said that net tangible assets fell from 0.01 cents per share last year to nil this year, with diluted loss per share up 50 percent to 0.03 cents.
Invion said it had cash and cash equivalents of $1,036,818 at June 30, 2021 compared to $618,843 at June 30, 2020.
Invion fell 0.1 cents or 6.7 percent to 1.4 cents with 3.8 million shares traded.

4D MEDICAL

4D Medical says it will trial its XV lung ventilation analysis software (LVAS) to validate interventional pulmonary treatments, with unnamed US collaboration partners.
4D said in a media release, not announced on the ASX, that the interventional pulmonology, or lung treatment, market was valued at $US1.3 billion and was expected to be $US1.75 billion by 2026.
The company said that interventional pulmonology was the use of minimally-invasive procedures to diagnose and manage a wide range of thoracic diseases.
4D said that the program was the “realization of the business-to-business potential of XV technology … sought by medical device manufacturers and the pharmaceutical industry as a trusted means of validating therapeutic interventions”.
The company said that “enhancing healthcare industry research on a commercial basis and through reimbursement contracts represents a widening of revenue streams … employing its respiratory imaging capability as a complementary technology for innovative procedures and third-party product development”.
4D head of medical and clinical affairs Dr Jason Kirkness said the program would “validate approaches that use a combination of endoscopic techniques and functional lung imaging instead of surgery, offering faster diagnosis, quicker recovery time and less pain”.
“In simple terms, this is a non-invasive way to visualize the extent of the diseased portions of the lung,” Dr Kirkness said. “Interventional pulmonologists work in multi-disciplinary team of specialists, including thoracic surgeons, oncologists, radiologists, critical care physicians and respiratory therapists, tailoring a treatment plan for each patient.”
“Functional lung imaging can help in management of advanced disease in such a teams-based approach, empowering interventional pulmonologists through innovation and ensuring every patient receives the highest quality of care,” Dr Kirkness said.
4D said that the trial of its software for pulmonary intervention would be supervised by Dr Kirkness and was “one of several across multiple US tertiary health systems, focused upon functional lung imaging in patients with progressive and advanced lung diseases that result in moderate to severe decline in quality of life”.
4D managing-director Dr Andreas Fouras said the company was “working in close collaboration with commercial partners of global stature in the medtech and pharmaceutical sectors, and with global key opinion leaders who recognize the value of our XV technology in differentiating disease processes, in assisting at decision points and enabling advanced personalized medicine”.
“Beyond providing a clinical information resource to healthcare providers, the ability of our technology to validate product innovation in medical devices and drug discovery opens up a significant parallel revenue stream,” Dr Fouras said.
4D was up one cent or 0.7 percent to $1.46.

NEUREN PHARMACEUTICALS

Neuren says its US trofinetide partner Acadia has completed enrolment in the phase III trial of trofinetide in Rett syndrome, with results expected by the end of the year.
In 2019, Neuren said that Acadia Pharmaceuticals had begun the 180-patient, randomized, double-blind, placebo-controlled 'Lavender' trial (BD Oct 31, 2019).
In 2018, the company said Acadia would pay $630 million in upfront fees, milestones and royalties for North American rights to trofinetide (BD: Aug 7, 2018).
Today, Neuren said the trial was investigating 12 weeks of treatment with trofinetide compared with placebo.
The company said that Rett syndrome was a debilitating neuro-developmental disorder affecting up to one in 10,000 females worldwide, with a range of severe impairments emerging in infancy, affecting the child's ability to speak, walk, eat and breathe.
Neuren said the trofinetide Rett program had US Food and Drug Administration fast track, orphan drug and rare paediatric disease designations.
Neuren chief executive officer Jon Pilcher said completion of enrolment was "a very important milestone for Neuren".
"Given the many challenges presented by the pandemic over the last 18 months, this is a great achievement by Acadia and reflects the remarkable commitment and determination of the Rett syndrome community in the United States," Mr Pilcher said.
Neuren said that positive results should enable trofinetide sales in Europe and Asia.
Neuren was up 10 cents or 6.25 percent to $1.70.

TELIX PHARMACEUTICALS

Telix says it has dosed the first of up to 15 patients in its first-in-human, 'Cupid', phase I study of TLX592 for advanced prostate cancer.
Telix said the study would evaluate the safety, tolerability, pharmacokinetics, biodistribution and radiation dosimetry of TLX592, or 64-copper-prostate specific membrane antigen (64-Cu-PSMA).
The company said the study was being conducted with Sydney's Genesiscare and initially would use copper-64-labelled TLX592 as a positron emission tomography (PET) imaging agent, to evaluate bio-distribution and dosing, before proceeding to studies with actinium-225 as a 'targeted alpha therapy' or TAT.
Telix said that TLX592 targeted prostate specific membrane antigen, as did its existing TLX591 (177-lutetium-rosapatamab) prostate cancer therapy program.
The company said that TLX592 was engineered with its Radmab antibody technology to clear more rapidly from a patient's circulation than unmodified antibodies, while maintaining TLX591's specificity for tumor-expressed PSMA and liver clearance, making it potentially more suitable for use as a targeting agent for 225-actinium, a potent therapeutic alpha emitting radio-nuclide.
Genesiscare principal investigator Prof Nat Lenzo said the start of the study was "a significant milestone in the development of next generation alpha particle treatments".
"The very high energy, short-range properties of targeted alpha therapy have the potential to offer a potent and highly selective anti-cancer therapy," Prof Lenzo said.
Telix chief executive officer Dr Christian Behrenbruch said that TLX592 was the company's "most significant proprietary antibody development to date".
"It is our aim to develop this program for both the early stages of metastatic prostate cancer, as well as for later stage patients no longer responding to lutetium therapy, in tandem with the 177-Lu-based TLX591," Dr Behrenbruch said.
Telix fell one cent or 0.2 percent to $5.29.

IMMUTEP

Immutep says it has dosed the first of up to 20 patients in its first-in-human, phase I, 'Insight-003' trial of IMP321 for solid tumors.

Immutep said the study would evaluate the safety, tolerability, and initial efficacy of 30mg subcutaneous doses of IMP321, or eftilagimod alpha, every two weeks in conjunction with standard of care chemotherapy and anti-programed death-1 (PD-1) therapy.

The company said the Insight-003 trial was an investigator-initiated study conducted by Frankfurt's Institute of Clinical Cancer Research IKF at Krankenhaus Nordwest.

Immutep said it was being run as the third arm, or stratum C, of the ongoing phase I Insight trial, with Prof Salah-Eddin Al-Batran as lead investigator.

Immutep chief medical officer Dr Frédéric Triebel said the trial was "the first time a triple combination therapy consisting of efti plus anti-PD-1 plus chemo is administered".

"Dosing the first patient in this trial is a significant milestone and it sets the wheels in motion for reporting first data which are currently anticipated in 2022," Dr Triebel said.

Immutep was up one cent or two percent to 51 cents with 2.4 million shares traded.

IMUGENE

Imugene says it will combine its CF33-CD19 oncolytic virus with Celularity's placental-derived Cycart-19 to develop an immunotherapy for solid tumors.

Imugene said that the Florham Park, New Jersey-based Celularity was developing allogeneic, or off-the-shelf, placental-derived T-cells therapies and the companies would begin in-vitro and in-vivo, non-clinical studies this year.

The company said that Celularity's CD19 therapy had shown sustained T-cell growth with continuous killing of tumor cells in-vivo and combining its oncolytic virus technology had "the potential to become a novel approach to improve outcomes … [in] solid tumors".

Imugene said that Cycart-19 was a placental-derived T-cell investigational therapy engineered with a chimeric antigen receptor (CAR) that was cryo-preserved and would be available off-the-shelf.

Imugene managing-director Leslie Chong said "the synergy between Celularity's placental derived cells and our Oncarlytic platform has the potential to shift the cellular medicine paradigm".

"In pre-clinical studies Celularity's cellular therapies have shown the ability to overcome limitations that have hindered other approaches, including increased proliferation and persistence in vivo, resistance to T-cell exhaustion and low immunogenicity, which allows for repeated dosing," Ms Chong said.

Imugene fell one cent or 3.4 percent to 28.5 cents with 73.3 million shares traded.

DORSAVI

Dorsavi says it has extended its agreement with Medtronic for a further six months in a contract worth about $US171,000 ($A231,260).

Dorsavi said the agreement extension was beyond the $US330,000 master service agreement with the Dublin-based Medtronic to test its wearable sensors to assess patients undergoing surgical evaluation (BD: Dec 9, 2020; Mar 30, 2021).

Dorsavi chief executive officer Dr Andrew Ronchi said "the extension of our agreement … is a strong validation of our world-leading technology".

"This agreement further highlights the different potential uses of our technology, exploring new applications and potential partnerships," Dr Ronchi said.

Dorsavi was unchanged at 2.6 cents with 8.7 million shares traded.

PHARMAXIS

Pharmaxis says PXS-5505 with chemotherapy improves survival, delays tumor growth, and reduces intra-tumoral pressure in mice with cholangio-carcinoma.

Pharmaxis said that data from a pre-clinical study of PXS-5505 in the liver cancer, cholangiocarcinoma (CCA) was presented at the Americas Hepato-Pancreato-Biliary Association meeting in Miami, Florida.

The company said that New York's University of Rochester Medical Center researchers were investigating the role of lysyl oxidase (LOX) enzymes in liver cancer and whether PXS-5505 could improve the efficacy of current chemotherapy drugs by inhibiting the enzymes.

Pharmaxis said cholangio-carcinoma (CCA) was the second most frequently diagnosed primary liver malignancy and has nearly doubled in incidence over the last decade.

The company said that CCA had the presence of highly fibrotic tissue increased tumor stiffness and decreases drug perfusion.

The presentation said that the researchers examined tumor tissue specimens collected from patients over 10 years and found that LOX enzymes were "significantly elevated in human CCA and correlate with poor prognosis".

Pharmaxis said the combination of PXS-5505 with chemotherapy improved survival, delayed tumor growth and reduced intra-tumoral pressure in mice with cholangio-carcinoma.

The company said the researchers proposed that PXS-5505 with standard chemotherapy was "an innovative therapeutic strategy with potential for clinical translation in primary liver malignancy".

Pharmaxis chief executive officer Gary Phillips said the role of LOX enzymes in fibrosis was well-established and there was "a growing body of evidence that in cancers such as those of the liver and pancreas, the poor outcomes experienced with current chemotherapy regimens is due to fibrotic tissue restricting drug access and stimulating tumor growth".

Mr Phillips said that PXS-550 was an anti-fibrotic cancer drug and he was "very encouraged by the results … that show a potential disease modifying role for our drug in liver cancer".

"Exploring the potential of PXS-5505 to address liver cancers such as cholangiocarcinoma or other cancers where fibrosis is limiting the clinical benefit of current chemotherapy is something we will continue to assess with our scientific and clinical collaborators," Mr Phillips said.

Pharmaxis was up 0.1 cents or 1.05 percent to 9.6 cents with 5.2 million shares traded.

NOXOPHARM

Noxopharm says Veyonda, also known as idronoxil or NOX66, enhances the cancer-killing effect of 177-lutetium-PSMA-617 radiation in mice.

Noxopharm said that University of Queensland research showed the combination had a "synergistic therapeutic response, with sustained and almost complete regression of the tumor and minimally-observed systemic toxicity" not observed in any mice treated with a monotherapy.

The company said the mice were dosed with 177-lutetium-PSMA-617 radiation once with the equivalent of a human dose, with idronoxil dosed rectally twice daily for 10 days.

Noxopharm said that the combination provided "full regression of most of the tumors, to the extent that median overall survival could not be determined".

Noxopharm was up half a cent or 0.9 percent to 58 cents.

EMYRIA

Emyria says it will work with the University of Western Australia on 3,4-methylene-dioxy-meth-amphetamine (MDMA, or 'ecstasy') compounds for neurological disorders.
Emyria said it would pay the University Australia a minimum of $491,000 over 12 months to work on MDMA-like compounds or analogues.
The company said the collaboration would assist it "in becoming a leader in the development of psychedelic-assisted therapies and treatments for major neurological disorders".
Emyria said that the University of Western Australia's Dr Matt Piggott would lead the program.
The company said that MDMA analogues had shown promise for post-traumatic stress disorder, as well as neurological disorders such as Parkinson's disease.
Emyria managing-director Dr Michael Winlo said "MDMA-assisted psychotherapy has demonstrated huge potential in treating severe post-traumatic stress disorder and Emyria is actively working to develop a safe and scalable delivery model for this treatment".
"Emerging treatments like psychedelic-assisted therapy have great potential but require further investment and innovation into new drugs, digital technologies and care models in order to improve efficacy, safety and access for patients," Dr Winlo said.
Emyria was up half a cent or 2.9 percent to 18 cents.

ALTERITY THERAPEUTICS

Alterity says that the US Patent and Trademark Office has allowed a composition of matter patent relating to iron implication in neuro-degenerative diseases.
Alterity said that, when granted, the patent, titled 'Compounds for and Methods of Treating Diseases' would secure exclusivity "for a new group of iron chaperones designed to redistribute the excess iron implicated in many neuro-degenerative diseases, including Alzheimer's and Parkinson's" until 2041.
The company said the patent covered more than 80 novel compounds and underwent prioritized examination by the USPTO.
Alterity said that together with the recent grant of a separate US patent for claims on a separate group of more than 150 compounds, it was "in a strong position with respect to its iron chaperone technology to address neuro-degeneration".
Alterity fell 0.3 cents or 8.1 percent to 3.4 cents with 13.05 million shares traded.