Biotech Daily

Wednesday October 13, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ANTISENSE UP 11%; IMUGENE DOWN 6%**

*** PROTAGONIST JUMPS 94% AS FDA LIFTS RUSFERTIDE HOLD**

*** IDT, MIPS $2m SARS-COV-2 mRNA VACCINE MANUFACTURING DEAL**

*** PHARMAXIS DOSES FIRST OF 24 PATIENTS IN PXS-5505 PHASE II TRIAL**

*** RESONANCE: 'LIVERSMART TO LAUNCH THIS YEAR'**

*** AUSCANN: MARIJUANA DERMACANN SAFE IN DOGS AT 5mg/kg**

*** PARADIGM PPS REDUCES ARDS LUNG INFLAMMATION, IN MICE**

*** PRESCIENT IN-VITRO DATA BACKS OMNICAR**

*** US PATENT FOR REDHILL'S TALICIA FOR HELICOBACTER PYLORI**

*** AUDEARA APPOINTS OAKTREE US HEADPHONE DISTRIBUTOR**

*** ACTINOGEN RECEIVES $1.4m FEDERAL R&D TAX INCENTIVE**

*** KAZIA 2.5m M-D DR JAMES GARNER OPTIONS AGM**

*** BIO-MELBOURNE, CYTIVA TRANSLATION FUNDING**

MARKET REPORT

The Australian stock market fell 0.11 percent on Wednesday October 13, 2021, with the ASX200 down 8.2 points to 7,272.5 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 12 fell and five traded unchanged.

Antisense was the best, up 2.5 cents or 11.1 percent to 25 cents, with 7.2 million shares traded. Resonance climbed 9.2 percent; Impedimed improved 7.7 percent; Alterity and Prescient were up more than six percent; Compumedics was up 5.1 percent; Pharmaxis climbed four percent; Medical Developments and Uscom were up more than three percent; Mesoblast, Optiscan and Patrys rose more than two percent; Avita, Clinuvel, Cyclopharm, Genetic Signatures and Volpara were up more than one percent; with CSL, Opthea, Paradigm, Polynovo, Pro Medicus and Telix up by less than one percent.

Imugene led the falls, down 2.5 cents or 5.95 percent to 39.5 cents, with 17.4 million shares traded. Amplia, Oncosil, Osprey and Proteomics lost more than two percent; Cynata, Neuren and Universal Biosensors were down more than one percent; with Cochlear, Kazia, Nanosonics, Orthocell, Resmed and Starpharma down by less than one percent.

PROTAGONIST THERAPEUTICS

Queensland's Nasdaq-listed Protagonist recovered 94 percent to $US35.36 ($A48.16) following the removal of a US regulatory hold on its rusfertide cancer studies.

On October 11 (US time) Protagonist said the US Food and Drug Administration had removed the full clinical hold on its rusfertide clinical studies and all clinical studies of rusfertide could be resumed.

Following the announcement, company climbed $US17.12 or 93.9 percent from $US18.24 to $US35.36, with 45,683,600 shares traded.

Last month, Protagonist fell 62.0 percent to $US17.53 ($A24.08) following the FDA placing a clinical hold on its rusfertide cancer studies (BD: Sep 20, 2021.

The company said that dosing of patients in all ongoing clinical trials with rusfertide, or PTG-300, would be put on hold and study investigators had been contacted to facilitate patient notification.

Protagonist said it had notified the FDA of "benign and malignant subcutaneous skin tumors" observed in a 26-week "rasH2 transgenic mouse model" toxicology study.

"The rasH2 model is designed to detect signals related to tumorigenicity, and benign and malignant subcutaneous skin tumors were observed in this study," the company said on its website.

Protagonist said it had provided the FDA with all requested information as the basis for a complete response and subsequent removal of the clinical hold, including individual patient clinical safety reports, the updated investigator brochure and patient informed consent forms, and had performed a comprehensive review of the most recent safety database, and included new safety and stopping rules in the study protocols.

The company said that the rasH2 mouse signal "also prompted a re-examination of the four cases of cancer observed across all rusfertide clinical trials involving over 160 patients, and a comprehensive review of the safety database, including cases of suspected unexpected serious adverse reactions".

"No additional cancer cases, and no other unexpected safety signals, surfaced in this process," Protagonist said.

Protagonist chief executive officer Dr Dinesh Patel said the company was "extremely pleased that the FDA has acted so quickly in lifting the clinical hold on the rusfertide development program, allowing us to resume patient dosing in our clinical studies".

"Patient safety continues to be our topmost priority," Dr Patel said.

"We believe that the cumulative evidence regarding the safety and clinical risk-benefit of rusfertide is supportive of expedited clinical development," Dr Patel said.

"We are actively preparing to initiate the phase III registrational study for polycythemia vera in the first quarter of 2022," Dr Patel said.

"Protagonist will continue to work closely with the FDA to ensure patient safety with amendments to current and planned future studies with rusfertide," Dr Patel said.

"We remain optimistic about the future potential of rusfertide to address unmet medical needs in excessive erythrocytosis and iron overload related diseases like polycythemia vera and hereditary hemochromatosis, respectively," Dr Patel said.

Last year, Protagonist said that early data from its 50-patient, phase II trial of PTG-300 for the blood cancer polycythemia vera showed a "robust clinical response" and dose-related effects (BD: Jun 1, 2020).

Last night on the Nasdaq, Protagonist fell $US3.64 or 10.29 percent to $US31.72 ($A43.21) with 4,749,597 shares traded.

IDT AUSTRALIA

IDT says it will manufacture a severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) mRNA vaccine for the Monash University's Institute of Pharmaceutical Sciences.
IDT said the agreement was valued at $1,999,999 to produce drug product for the Institute's mRNA Sars-Cov-2 receptor binding domain vaccine clinical trial.
The company said the Federal Department of Health had consented to it using its sterile manufacturing facilities.
Earlier this year, the company said the Federal Government Department of Health requested a feasibility assessment of its sterile manufacturing facility for the production Covid-19 vaccines and IDT was in discussions with the Victorian Government, mRNA Victoria and the Monash Institute of Pharmaceutical Sciences (MIPS) for potential vaccine manufacture (BD: Mar 19, June 22, 2021).
Today, IDT said that the MIPS vaccine project was funded by mRNA Victoria and the Federal Medical Research Future Fund, with a clinical trial hoped to begin by the end of this year.
The company said that MIPS would supply the bulk raw materials, including up to 200mg of mRNA drug substance encoding part of the severe acute respiratory syndrome coronavirus-2 (Sars-CoV-2) spike protein, excipients, lipids and polymers.
IDT said its total fees of $1,999,999 were "based on achieving certain project milestones in relation to the … manufacturing activities".
IDT said all intellectual property rights in any background intellectual property remained with the party that contributed the background intellectual property and all intellectual property rights in the services intellectual property vested with Monash.
IDT chief executive officer Dr David Sparling said he appreciated the Federal Government support in having the sterile manufacturing facility ready for a project of this nature and allowing IDT to use the facility for the work.
"Being Australia's first locally developed mRNA Covid-19 vaccine, all of the team here at IDT are excited to be a part of the MIPS project," Dr Sparling said.
"It is a great opportunity for IDT to develop and showcase our [clinical good manufacturing practice] manufacturing capabilities in mRNA product manufacture," Dr Sparling said.
IDT was up half a cent or 0.8 percent to 60 cents with 1.5 million shares traded.

PHARMAXIS

Pharmaxis says it has dosed the first of 24 patients in its phase II trial of PXS-5505 for the bone marrow cancer myelofibrosis.
Last week, the company said that the phase Ic dose-ranging trials of PXS- 5505 for the myelofibrosis had shown "inhibition of the target enzymes, LOX and LOXL2, at greater than 90 percent over a 25-hour period at day-7 and day 28" and the study would progress to the phase II dose expansion phase, in which 24 patients would be treated twice a day with the unstated highest dose for six months (BD: Oct 5, 2021).
Today, Pharmaxis said the phase II trial aimed to demonstrate that PXS-5505 was safe and tolerable in myelofibrosis patients, who were intolerant, unresponsive or ineligible for treatment with approved JAK-inhibitor drugs.
The company said the trial's secondary endpoints were to explore the impact of inhibiting lysyl oxidase enzymes on a number of disease parameters such as bone marrow fibrosis, cytopenia and spleen volume.
Pharmaxis said trial sites were open to recruit patients in Australia and South Korea with preparations "well advanced" to open more sites in Taiwan and the US.
Pharmaxis was up half a cent or four percent to 13 cents.

RESONANCE HEALTH

Resonance says it is developing an artificial intelligence-enabled medical device, Liversmart for reporting iron and fat in livers.
Resonance said Liversmart combined its two regulatory-cleared products, Ferrismart and Hepafat-AI into a single multi-parametric magnetic resonance imaging (MRI) session, avoiding the need for multiple MRI appointments, for a more complete and comprehensive assessment of a person's liver.
The company said Liversmart might be eligible for two new US current procedural technology (CPT) codes published by the American Medical Association (AMA) which would become active on January 1, 2022.
Resonance said Liversmart's use remained subject to regulatory clearances including with the US Food and Drug Administration which was expected to take about 45 days from submission, or longer if the FDA had queries.
Resonance said Liversmart was undergoing final quality and verification checks and it would submit the application for FDA clearance "within the coming weeks".
Resonance managing-director Mitchell Wells said Liversmart "responds to the growing trend in medical imaging for more holistic assessment of human organs using [artificial intelligence] for rapid turnaround and enhanced scalability".
"Liversmart … leverages our global standing in liver-iron and liver-fat assessment through our existing regulatory-cleared liver products," Mr Wells said.
"Liversmart provides a more complete assessment of the liver by combining multiple MRI appointments and assessments into a singular multi-parametric scanning session which will enhance patient convenience and should reduce cost," Mr Wells said.
"Importantly, we believe that Liversmart may be eligible for two new United States category III CPT codes and we are now awaiting a definitive determination from a US code certifier," Mr Wells said.
"If the codes are determined to be applicable to Liversmart this will represent a major milestone on our pathway to more widespread reimbursement in the US," Mr Wells said.
Resonance was up 0.8 cents or 9.2 percent to 9.5 cents.

AUSCANN

Auscann says a 15-dog, 90-day study of marijuana-based Dermacann shows the dermatology product is safe and tolerable at up to five times the daily recommended dose.
Auscann said that Dermacann was in development for anti-inflammatory and immune support for dogs with skin conditions.
The company said that the study at an unnamed US veterinary research site treated five dogs with 3mg/kg Dermacann and 5mg/kg Dermacann for 92 days and said the doses were "clinically well tolerated with no clinically relevant nor statistical differences between treated and [the five] control dogs".
Auscann said all other clinical chemistry results were normal, supporting Dermacann to be "safe and effective product for use in dogs at up to 5 [times] the planned dose".
Auscann said it submitted the second data module for the registration of Dermacann to the Australian Pesticides and Veterinary Medicines Association.
In July, the company said Dermacann "was shown to be safe and effective at reducing inflammatory skin lesions in dogs diagnosed with atopic dermatitis" (BD: Jul 20, 2021).
Today, Auscann said it would submit its final data modules on efficacy, safety and environment, to the Australian Pesticides and Veterinary Medicines Association on receipt of the final report for the target animal safety study, expected by this year.
Auscann was up 0.2 cents or 2.3 percent to 8.9 cents with 1.7 million shares traded.

PARADIGM BIOPHARMA

Paradigm says pentosan polysulfate sodium (PPS) reduces lung inflammation for acute respiratory distress syndrome (ARDS) in a proof-of-concept model in mice.
Paradigm said pentosan polysulfate sodium was administered subcutaneously at 3mg/kg and 6mg/kg resulted in a significant reduction in weight loss, compared to control mice.
The company said pentosan polysulfate sodium which was administered at 3mg/kg demonstrated a “statistically significant improvement in blood oxygen saturation at eight days post infection compared to vehicle treated controls”.
Paradigm said 3mg/kg PPS resulted in a statistically significant reduction in inflammatory cell infiltrates in the lungs at eight days post-infection, coupled with the presence of infiltrating cellular aggregates in the lung tissue where inflammation was most severe.
The company said the infiltrating cellular aggregates were reduced in PPS-treated mice.
Paradigm was up one cent or 0.5 percent to $1.88 with 1.1 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says that in-vitro data shows its Omnicar has a cancer killing dose-response, has high potency and can be “re-armed” and directed at different cancers.
Prescient said the data would be presented at the Cell & Gene Meeting in Carlsbad, California from October 11 to 14, 2021.
The company said that Omnicar showed a dose-response for cancer killing activity and high potency, that Omnicar-T-cells could be “re-armed” and that sequential arming could re-direct Omnicar-T cells from one cancer antigen to another.
Last year, Prescient said it licenced an immune receptor platform from the University of Pennsylvania and a molecular binding system from Oxford University (BD: May 26, 2020).
The company said at the time that the immune receptor and molecular binding technologies would be combined to develop a chimeric antigen receptor (CAR) cell therapy platform named Omnicar, which would enable T-cell activity control and multi-antigen targeting with a universal cell product.
Today, Prescient said that Omnicar’s modular CAR system decoupled antigen recognition from the T-cell signalling domain.
The company said it was developing Omnicar programs for acute myeloid leukaemia, human epidermal growth factor receptor 2 positive (HER2+) and solid tumors, including breast, ovarian and gastric cancers, and glioblastoma multiforme.
Prescient said that Omnicar-T-cells pre-armed with HER2 binders showed “potent ability to kill cancer cells expressing HER2”.
“The cells were then washed and rested for seven days, resulting in unarmed Omnicar cells [and] these same Omnicar-T cells were then capable of being re-armed with HER2 binders, and once again demonstrated targeted killing,” the company said. “Not only were re-armed Omnicar-T cells capable of antigen-directed killing, but re-armed cells exhibited the same levels and kinetics of cytotoxicity of pre-armed Omnicar-T cells.”.
“Omnicar cells can be unarmed, re-armed and still kill with near identical fidelity … another example of the flexible yet predictable activity of Omnicar cells,” Prescient said.
“The new results demonstrate important capabilities of Omnicar to deliver next generation cell therapies that are controllable and able to target multiple cancer antigens,” the company said.
“These are important milestones not only in the development of Prescient’s in-house Omnicar programs, but in the development of the overall platform and demonstrating novel features relevant to potential partners and collaborators,” Prescient said.
Prescient was up 1.5 cents or 6.8 percent to 23.5 cents with 5.3 million shares traded.

REDHILL BIOPHARMA

Israel's Redhill says the US Patent and Trademark Office has granted its patent relating to Talicia for the treatment of Helicobacter pylori infection in adults.
Redhill said the patent, titled 'Rifabutin-based compositions and methods for treating Helicobacter pylori infection' would protect its intellectual property until 2034.
In 2010, Redhill said it bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Redhill previously told Biotech Daily that it further developed Heliconda or RHB-105 for Helicobacter pylori, renaming it Talicia which was approved in 2019 by the US Food and Drug Administration (BD: Nov 5, 2019).
On the Nasdaq, Redhill fell six US cents or 1.26 percent to $US4.69 ($A6.39) with 332545 shares traded.

AUDEARA

Audeara says it has appointed the Chesterfield, Missouri-based Oaktree Products Inc as a distributor for its A-01 headphone for personalized sound and product bundle.
Audeara said Oaktree provided more than 4,200 products to hearing professionals.
The company said it had received the first order from Oaktree, with its products available on Oaktree's website.
Audeara was up one cent or eight percent to 13.5 cents.

ACTINOGEN MEDICAL

Actinogen says it has received $1,435,713 rebate from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Actinogen said the incentive related to expenditure for the year to June 30, 2021.
Actinogen was unchanged at 11 cents with 1.65 million shares traded.

KAZIA THERAPEUTICS

Kazia says its annual general meeting will vote to issue 2,500,000 options to managing director Dr James Garner.
Kazia said it would issue 1,000,000 options to Dr Garner in relation to his performance for the year to June 30, 2020, exercisable at $1.185 each by November 11, 2025 and vesting in four equal tranches over four years from January 4, 2022.
The company said it would issue 1,500,000 options to Dr Garner based on his performance in the year to June 30, 2021, exercisable at a 43 percent premium to the 5-day volume weighted average price on the issue date, which was expected to be about $2.20 each, and expiring on November 11, 2025.
Kazia said the options would vest in three equal tranches over three years from November 11, 2022.
Kazia said shareholders would vote on the remuneration report, the re-election of director Iain Ross, the employee share option plan, the prior issue of placement shares and the approval of an additional placement facility.
The meeting will be held virtually on November 10, 2021 at 10am (AEDT).
Kazia fell half a cent or 0.35 percent to $1.435.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it is co-hosting an event with Cytiva, titled ‘Is your biologic molecule trapped on the bench?’.

The Network said that Cytiva was owned by the Boston-based General Electric and the company described itself as a “provider of technologies and services that advance and accelerate the development and manufacture of therapeutics”.

The Bio-Melbourne Network said the event would “provide insight into the [Australia and New Zealand] Bio-Challenge, which offers $360,000 worth of awards to scientists trying to get their bio-therapeutic molecules to make the jump from the bench to the clinic”.

The Network said that guest speakers at the event include Cytiva executives Tim O’Meara and Stephen O’Sullivan, as well as the University of Technology Sydney’s Biologics Innovation Facility manager Edwin Huang.

The Network said the virtual event will be held on October 14, 2021 from 4pm to 4:50pm (AEDT) and for further details and to register, go to: https://biomelbourne.org/event/bioforum-what-is-the-cytiva-anz-biochallenge/.