Biotech Daily

Tuesday November 9, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PHARMAXIS UP 14%; ACTINOGEN DOWN 13%**

*** REDHILL: KUKBO INVESTS UP-TO $13.5m FOR ASIAN RIGHTS**

*** RAGE $3.7m FROM IP GROUP, MONASH; DR CHRIS WRAIGHT CEO**

*** PHARMAXIS: FDA CLEARS PXS-5505 PHASE II LIVER CANCER TRIAL**

*** ACTINOGEN: FDA APPROVES XANAMEM FOR FRAGILE X TRIAL**

*** ISLAND PAYS NY STATE UNIVERSITY $914k FOR DENGUE FEVER TRIAL**

*** RACE: WOLLONGONG UNI TO EVALUATE ZANTRENE FORMULATIONS**

*** ARTRYA 'PREFERRED SUPPLIER' TO UK NHS HOSPITALS**

*** LIVING CELL RECEIVES $381k NZ R&D TAX CREDIT**

*** REGAL TAKES 7.7% OF MEDADVISOR**

*** CRESO LOSES 3-DAY CONSULTANT DR BRIAN WALKER MLC**

MARKET REPORT

The Australian stock market fell 0.24 percent on Tuesday November 9, 2021, with the ASX200 down 18.0 points to 7,434.2 points. Nineteen of Biotech Daily Top 40 stocks were up, 16 fell and five traded unchanged. All three Big Caps were up.

Pharmaxis was the best, up 1.5 cents or 13.6 percent to 12.5 cents, with 2.4 million shares traded. Alterity and Optiscan climbed more than seven percent; Immutep and Oncosil were up more than six percent; Paradigm and Starpharma improved more than four percent; Genetic Signatures, Imugene and Uscom were up more than three percent; Next Science, Patrys and Telix rose two percent or more; Kazia, Mesoblast, Nova Eye and Resmed were up more than one percent; with Clinuvel, Cochlear, CSL, Opthea and Polynovo up by less than one percent.

Actinogen led the falls, down 2.5 cents or 13.2 percent to 16.5 cents, with 18.8 million shares traded. Avita lost 9.8 percent; Cynata shed five percent; Antisense, Compumedics, Cyclopharm and Osprey fell four percent or more; Neuren and Prescient were down more than three percent; Amplia and Volpara shed more than two percent; Nanosonics and Proteomics were down more than one percent; with Medical Developments, Pro Medicus and Universal Biosensors down by less than one percent.

REDHILL BIOPHARMA

Redhill says Kukbo Co will invest up to $US10 million ($A13,523,840) for the first rights to opaganib, RHB-107 and Talicia (Heliconda) for South Korea and other Asian territories.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Today, the company said it had received the first $US5 million tranche which was priced at $US6.04 a share, a 20 percent premium on the 30-days volume weighted average price to November 8, 2021.
Redhill said that the second tranche of $US5 million would be paid within six months, subject to conditions.
The company said that Kukbo had “a right of first offer, for a period of six months, for a licence with respect to one or more of … opaganib, RHB-107 (upamostat) and Talicia, for one or more of the territories of South Korea, Japan, Indonesia, Vietnam, Thailand and Malaysia.
In September, Redhill said that opaganib had missed the endpoints of its 475-patient phase II/III trial for severe Covid-19 pneumonia (BD: Sep 15, 2021).
In 2019, the company said the US Food and Drug Administration had approved Talicia delayed-release capsules for Helicobacter pylori infection (BD: Nov 5, 2019).
Today, Redhill chief executive officer Dror Ben-Asher said the company was “rapidly advancing with opaganib’s Covid-19 data package submissions to regulators in several territories including the US, EU and others, ahead of planned regulatory advice”.
The company said that the Irvine, California-based Nexpedia Holdings and the Red Bank, New Jersey-based Network 1 Financial Securities facilitated the introduction between the parties.
On the Nasdaq, Redhill was up three US cents or 0.59 percent to $US5.10 ($A6.89) with 315,656 shares traded.

RAGE BIOTECH

Rage says it has raised $3.7 million from London’s IP Group, with support from Monash Investment Holdings and appointed Dr Christopher Wraight chief executive officer.
Last year, Rage said it hoped to raise up to $10 million from IP Group, Monash University and the University of Western Australia for the development of inflammatory lung disease treatments (BD: Jul 9, 2020).
Today, the company said it would use the funds to further develop drugs to inhibit “the” (Rage), which it said was an important therapeutic target in a wide range of inflammatory diseases.
Rage said that the company was founded on intellectual property co-developed at Melbourne’s Monash University, the University of Western Australia, Murdoch University and the Baker and Perron Institutes, with exclusive technology licences to inhibitors Rage.
The company said that its most advanced drug was an RNA therapeutic, a splice-switching oligonucleotide, which was being developed to be inhaled to target lung diseases where inflammation and scarring were a problem.
Rage said it had appointed Dr Wraight as chief executive officer and a director.
The company said that Dr Wraight had experience in early-stage pharmaceutical research and development and commercialization and previously was Antisense’s research director.
Rage said that Dr Wraight held a Bachelor of Science, a Master of Business Administration and a Doctor of Philosophy from Melbourne’s La Trobe University.
Rage is a private company.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has cleared a phase II trial of PXS-5505 with chemotherapy for unresectable hepatocellular carcinoma patients.
Pharmaxis said that the investigational new drug application was submitted by the New York State's University of Rochester Medical Center and followed positive pre-clinical results.
In August, the company said that PXS-5505 with chemotherapy improved survival, delayed tumor growth, and reduced intra-tumoral pressure in mice with cholangio-carcinoma (BD: Aug 5, 2021).
Today, Pharmaxis said that PXS-5505 would be added to the current chemotherapy standard-of-care; a combination of a programmed death ligand-1 (PD-L1) inhibitor and an anti-vascular endothelial growth factor (VEGF) drug as first line therapy in newly diagnosed patients with unresectable liver cancer.
The company said that it was in negotiations with the University of Rochester, which led its pre-clinical studies of PXS-5505, to start the phase II trial in 2022.
Pharmaxis said the dose-escalation trial, in an undisclosed number of patients, would assess the safety of PXS-5505 with a PD l-1 inhibitor and an anti-VEGF drug.
The company said that it would explore the impact of PXS-5505 on fibrosis and drug perfusion, which would be followed by a six-month trial of the selected dose with both safety and efficacy endpoints.
Pharmaxis was up 1.5 cents or 13.6 percent to 12.5 cents with 2.4 million shares traded.

ACTINOGEN MEDICAL

Actinogen says the US Food and Drug Administration has approved its investigational new drug application for a 50-patient phase II trial of Xanamen for fragile-X syndrome.
Actinogen said the phase II, double-blind, randomized, placebo-controlled trial would assess the safety, tolerability, and efficacy of the Xanamem in male adolescents and young adults with Fragile X syndrome."
The company said that patients would be treated for 12-weeks and it expected results in 2023.
Actinogen said that it had a letter-of-intent with the Durham, North Carolina-based Worldwide Clinical Trials for the trial and would pay $944,724 "for start-up activities to enable prompt activation of sites".
Actinogen fell 2.5 cents or 13.2 percent to 16.5 cents with 18.8 million shares traded.

ISLAND PHARMACEUTICALS

Island says it will pay $US677,000 ($A913,855) to the State University of New York for an up-to 16-participant phase IIa trial of its anti-viral ISLA-101 Dengue fever treatment.
Island said the randomized, double-blind, placebo-controlled trial in up to 16 individuals would study the efficacy of ISLA-101 as a prophylactic for Dengue fever.
The company said that as part of the agreement, Dr Kristopher Paolino had been appointed principal investigator, and that any new discoveries to arise from the trial would be owned by Island.
Island chief executive officer Dr David Foster said "we are well on our way to initiating the [ISLA-101] study in early 2022" and it would take eight to 12 months to complete.
The company said that trial was titled the 'prophylactic examination of an antiviral in a dengue challenge model' (Peach) study.
Island fell half a cent or 1.6 percent to 30.5 cents.

RACE ONCOLOGY

Race says the University of Wollongong will evaluate long-acting peripheral intravenous and oral formulations of Zantrene, formerly bisantrene, for cancer.
Race said that currently Zantrene required a central catheter in a hospital.
The company said that “while this is standard practice for the delivery of many chemotherapy drugs, longer-acting and more patient-friendly routes of administration are desirable if the full market potential of Zantrene is to be achieved”.
Race said that the pre-clinical evaluations of the formulations would be led by Prof Marie Ranson.
Race was up five cents or 1.5 percent to $3.33.

ARTRYA

Artrya says it has been accepted “as a supplier of artificial intelligence software and platforms” for the UK National Health Service Shared Business Services Framework.
In October, the Perth, Western Australia-based Artrya said it hoped to raise $40 million at $1.35 a share to list on the ASX, about November 26, 2021, to develop its Salix arterial imaging software to detect plaque (BD: Oct 19, 2021).
Today, Artrya said it had been listed as an approved supplier for public organizations, including 1,250 NHS hospitals.
The company said that its Salix technology was “the only dedicated coronary artery disease diagnostic support [product] that provides an automated, comprehensive report to clinicians within 15 minutes”, including vulnerable plaque, a biomarker for cardiac arrest.
Artrya’s co-founder and managing-director John Barrington said the recognition was “significant and further validates the company’s European commercialization plans, and in particular, its focus in the UK”.
The company said it expected UK sales in mid-2022, with and Australia launch in early 2022.

LIVING CELL TECHNOLOGIES

Acrux says it has received $NZ394,240 ($A381,009) under New Zealand’s Research and Development Tax Loss Credit Scheme.
The company said that the R&D Tax Loss Credit gave New Zealand-based companies “an opportunity to cash-out a tax loss at the company tax rate of 28 percent as an alternative to carrying the tax loss forward, subject to meeting the tax requirements”.
The company said that the rebate related to research and development expenditure for the year to June 30, 2021.
Living Cell was unchanged at 0.8 cents with 2.1 million shares traded.

MEDADVISOR

Regal Funds Management says it has become a substantial share-holder in Medadvisor with 29,187,739 shares or 7.73 percent.
The Sydney-based Regal Funds said that between July 7 and November 4, 2021 it bought 13,230,000 shares for $4,930,150 or an average price of 37.3 cents a share.
Medadvisor fell 1.5 cents or 3.7 percent to 39.5 cents.

CRESO PHARMA

The Western Australia Legalise Cannabis Member of the Legislative Council Dr Brian Walker has resigned his consultancy with Creso Pharma.

Last week, Creso said it had appointed Dr Brian Walker as a consultant and chair of its Scientific Advisory Committee (BD: Nov 4, 2021).

Creso said at that time that Dr Walker was a medical practitioner, elected to the Western Australian Legislative Council and would oversee and provide input into its medical marijuana, hemp and psychedelic products.

The company said that as part of his remuneration package, it would issue Dr Walker 200,000 options, exercisable at 20 cents each by November 3, 2024.

Today, a staff member in Dr Walker's office told Biotech Daily that Dr Walker had resigned from the position on Monday November 8, 2021.

Dr Walker told Biotech Daily that he decided that, as a doctor and as a member of the Western Australia Parliament's Cannabis and Hemp Inquiry Committee, accepting the position "didn't pass the pub test" due to the conflation of psychedelics and cannabis.

Creso fell half a cent or 3.3 percent to 14.5 cents with 16.5 million shares traded.