Biotech Daily

Tuesday June 29, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 11%; ACTINOGEN DOWN 7%**

*** FEDERAL $19m FOR STEM CELL RESEARCH**

*** GILEAD $300k FELLOWSHIP GRANTS FOR 5 PROJECTS**

*** 4D MEDICAL: JOHNS HOPKINS JOINS XV LUNG TRIAL**

*** PHARMAXIS: LOW DOSE PXS-5505 SAFE, INHIBITS LOX, LOXL2 ENZYMES**

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*** EMYRIA APPOINTS DR ELI KOTLER FOR MDMA-PTSD TRIAL**

MARKET REPORT

The Australian stock market fell 0.08 percent on Tuesday June 29, 2021, with the ASX200 down 6.1 points to 7,301.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 22 fell, five traded unchanged and one was untraded.

Pharmaxis was the best, up 0.8 cents or 10.7 percent to 8.3 cents, with 25.8 million shares traded. Antisense climbed 7.7 percent; Compumedics and Neuren were up more than five percent; Oncosil and Resonance improved more than three percent; Clinuvel and Cynata rose two percent or more; Immutep and Pro Medicus were up more than one percent; with Cochlear, CSL, Nanosonics and Polynovo up by less than one percent.

Actinogen led the falls, down one cent or 7.1 percent to 13 cents, with 6.3 million shares traded. Imugene and LBT lost more than six percent; Patrys fell 5.2 percent; Avita and Impedimed were down four percent or more; Alterity, Cyclopharm and Starpharma lost three percent or more; Amplia, Dimerix, Genetic Signatures, Prescient, Universal Biosensors and Uscom shed more than two percent; Kazia, Medical Developments, Mesoblast, Resmed, Telix and Volpara were down one percent or more; with Opthea and Next Science down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it will provide $18.7 million for stem cell research.
A media release from the Minister for Health Greg Hunt said the funding would be distributed among 17 projects at 10 universities and research institutes for treatments, diagnostic tools and therapies “centred around stem cell use”.
The Government said the projects would be funded through the 2020 Stem Cell Mission to address diseases including Covid-19, Crohn’s disease, heart failure, neuroblastoma, Friedreich’s ataxia, epilepsy, kidney disease and digestive disease.
The media release said the University of Sydney would receive about $6.3 million for three projects, including work to develop a clinical trial for the use of stem cell grown heart muscle in patients with ‘no option’ end-stage heart failure.
The Government said that stem cell therapy was “a proven treatment for blood disorders such as leukaemia, Hodgkin’s disease and non-Hodgkin’s lymphoma”.

GILEAD SCIENCES AUSTRALIA AND NEW ZEALAND

Gilead says its 2021 Fellowship Research Grants Program has awarded $300,000 to five research projects.
Gilead said the research projects included Covid-19, HIV, hepatitis C elimination, chimeric antigen receptor T-cell (Car-T) therapy and fungal infections.
The company said the project recipients included University of Melbourne and St Vincent's Hospital’s Prof Kumar Visvanathan for research into the long-term general immunological responses in Covid-19 confirmed patients; the Kirby Institute’s Dr Benjamin Bavinton for research on the innovations and rapid adaptations to HIV testing, monitoring and care during Covid-19; and Pharmaceutical Research Services’ Andrew Pfeffer for engagement with local pharmacies to increase hepatitis C treatment uptake among people who inject drugs as part of a micro-elimination strategy.
Gilead said the Peter MacCallum Cancer Centre and Royal Melbourne Hospital’s Dr Adrian Minson won a grant for research into the kinetics of CAR-T-cell therapies and Monash University Central Clinical School’s Prof Orla Morrissey would be funded to determine the resistance rates to antifungal agents in chronic lung disease patients or post-lung transplant patients.

4D MEDICAL

4D Medical says that Johns Hopkins School of Medicine has begun recruiting participants for its XV lung ventilation analysis software (LVAS) trial.
In May, 4D said it had completed enrolment of the first cohort of eight of 70 participants at the University of Miami (BD: May 20, 2021).
The company said the trial would provide evidence of the capacity of its XV LVAS to evaluate and monitor patients suffering from progressive lung diseases such as emphysema and chronic bronchitis.
4D said that integrating its XV LVAS with the Baltimore, Maryland-based Johns Hopkins existing imaging equipment LVAS would “detect early changes in airway function, disease progression and regional ventilation defects in the lungs of approximately 15 [chronic obstructive pulmonary disease] patients”.
The company said the results would be compared to traditional respiratory diagnostics such as spirometry and computed tomography.
4D said the trial was expected to be completed this year.
4D climbed 9.5 cents or 8.1 percent to $1.265 with 1.1 million shares traded.

PHARMAXIS

Pharmaxis says data from the first dose of its dose-escalation trial shows “strong” inhibition of two target enzymes was found to be “highly statistically significant”.

In February, Pharmaxis said it had enrolled the first of 18 patients in the dose escalation phase of the phase Ic/IIa trial of PXS-5505 for myelofibrosis and earlier this month said it had completed dosing (BD: Feb 22, Jun 10, 2021).

According to the trial listing on the clinicaltrials.gov website, the dose escalation starts at 100mg twice daily for four weeks, but did not specify the second and third cohort doses.

Today, Pharmaxis said the trial showed inhibition of target enzymes LOX and LOXL2, good tolerability and consistent pharmaco-kinetic properties.

The company said the second dose cohort of the trial had been fully recruited and dosing of patients begun at sites in Australia and South Korea.

Pharmaxis said the safety and pharmaco-kinetics of the second dose would be assessed after 28 days, before starting the final and highest dose in the patients.

Pharmaxis said the dose escalation phase of the study would help select the optimal dose of PXS-5505 for its 24-patient, six-month, dose expansion phase IIa study to evaluate the safety and efficacy.

Pharmaxis chief executive officer Gary Phillips said that “along with excellent tolerability we are achieving levels of LOX and LOXL2 inhibition in myelofibrosis patients that are already exceeding those levels seen in the pre-clinical models of myelofibrosis”.

“In these models PXS-5505 caused disease modifying effects with improvements in blood cell count, diminished spleen size and reduced bone marrow fibrosis,” Mr Phillips said.

“Comparing these results with those achieved in the phase I study with healthy volunteers, we are now very confident that we will achieve a level of inhibition of the lysyl oxidase enzyme family that allows us to fully test the clinical relevance of these targets in myelofibrosis patients in the upcoming six-month dose expansion study,” Mr Phillips said.

Pharmaxis was up 0.8 cents or 10.7 percent to 8.3 cents with 25.8 million shares traded.

BIOTECH DAILY EDITORIAL POLICY: ADHERIUM, RESPIRI

Biotech Daily has reported that Respiri has made a scrip-only bid for Adherium, which has been rejected several times by the target company.

In April, Respiri offered one of its shares for seven Adherium shares, valuing Adherium at 2.25 cents a share or $19.14 million (BD: Apr 30, 2021).

In March, Adherium said it had raised $18 million in placement at 1.5 cents led by Trudell Medical and Bioscience Managers (BD: Mar 18, 2021).

The companies have filed their formal bidder’s and target’s statements for shareholders to consider and Biotech Daily has reported summaries of the two positions.

We shall not report any further discussion of the offer until investors have made their decisions.

We note that the Respiri bid was based on its 30-day volume-weighted average price to April 28, 2021, which was 15.77 cents, using the number of Adherium shares on issue prior to the $18 million placement.

While Adherium closed today at 1.7 cents, Respiri was at 6.7 cents, significantly changing the offer.

Adherium’s market capitalization at 1.7 cents is about $36.14 million, with the Respiri offer, including the placement shares, valuing it at $20.3 million.

GENETIC TECHNOLOGIES

Genetic Technologies has told the ASX that it had announced the planned end of May launch of its Covid-19 risk test in the US in April.
Genetic Technologies said it had drafted a Covid-19 test launch announcement on May 27, but only "received clearance" from the ASX on June 1, 2021.
In an 'aware' query, the ASX referred to the Genetic Technologies' announcement titled 'Covid-19 Risk Test Approved for Commercial Release' released on April 26, which said that, through the Piscataway, New Jersey-based Infinity Biologix LLC it had submitted an application to US regulators for its Covid-19 risk test (BD: Apr 27, 2021).
The ASX said that Genetic Technologies share price increased 37.5 percent from 0.8 cents on Thursday May 27 to 1.1 cents a share on the morning of Friday May 28 with a "very significant increase" in the volume of securities traded, and the company requesting a trading halt at 12.00pm on that day.
The ASX said that at 12.12pm on May 28, a post titled 'CV-19 SDR IBX Test Approved' was published on the Hotcopper social media website, but the announcement 'GTG COVID-19 Risk Test launched in USA' was not made by Genetic Technologies until Tuesday June 1, 2021, and was marked as market sensitive.
The ASX said the US Patent and Trademark Office disclosed that a patent, titled 'Computer Systems and Methods for Genomic Analysis', had been granted to Genetic Technologies on Tuesday June 8, (US time) a Twitter post was published on June 9 at 3.49am (AEST), followed by a post to Hotcopper at 9.40am (AEST).
The ASX noted a 35.6 percent jump in the company's American depository receipts (ADRs) with a "significant increase" in the volume of ADRs traded on Wednesday June 9 (US time) and the patent announcement was made to the ASX on Friday June 11
The ASX asked Genetic Technologies why it had not released the launch information prior to the morning of May 28 and when it had become aware of the patent grant.
Genetic Technologies told the ASX it first had confirmation of the launch on Saturday May 29, and it finalized the announcement draft on the morning of Monday May 31, and sent to the ASX for review, receiving clearance for release at 8.29am on Tuesday June 1, 2021.
Genetic Technologies said the patent grant which was available on Twitter on June 8, 2021 was not considered "material".
The company said the change in the price and increase in volume of its ADRs on the Nasdaq may have been the result of an announcement by Infinity Biologix on June 9 but was not considered to have had a material impact on the company's share price.
Genetic Technologies was unchanged at 0.9 cents with 12.2 million shares traded.

ELIXINOL WELLNESS (FORMERLY ELIXINOL GLOBAL)

Elixinol says it is terminating the agreement to buy Cannacare Health GmbH as it is "not in the best interests of … shareholders at this time".
In March, Elixinol said it would pay EUR9.0 million ($A13.9 million) up front, and up-to EUR24 million ($A37.0 million) for the Düsseldorf, Germany-based Cannacare Health GmbH (BD: Mar 15, 2021).
The company said at that time that it would pay EUR3.0 million in cash and EUR6.0 million in shares and on attainment of revenues of EUR12.9 million in the 2021 financial year, the maximum earn-out of EUR15.0 million would be payable in shares taking the total potential consideration to EUR24.0 million.
Today, Elixinol said completion was proposed to occur on July 5, but further due diligence revealed a changed German market outlook with rapidly intensifying competition.
Elixinol fell 1.5 cents or 11.5 percent to 11.5 cents with 4.4 million shares traded.

NYRADA

Nyrada says NYX-PCSK9i reduces low density lipoprotein, or 'bad' cholesterol by 46 percent on its own, and by up to 65 percent with atorvastatin (Lipitor), in mice.
Nyrada said that the 65 percent decrease compared with Lipitor alone which reduced low density lipoprotein by 27 percent.
The company said a dose of 50mg/kg was used and evaluated over 35 days with "no adverse effects identified" and NYX-PCSK9i "well-tolerated with no significant changes in food intake, body weight, or liver function observed".
Nyrada chief executive officer James Bonnar said "NYX-PCSK9i has shown very encouraging results in this recent cholesterol-lowering study, building our confidence it is the best drug candidate to take into human trials".
Mr Bonnar said it was the first pre-clinical study showing a cholesterol-reducing effect from an oral pro-protein convertase subtilisin/kexin type nine inhibitor drug when dosed in combination with a statin.
"It has the potential to provide a convenient and cost-competitive oral therapy for the 70 percent of patients at risk of cardiovascular disease who struggle to reach their target LDL cholesterol level despite taking a statin, such as Lipitor," Mr Bonnar said.
Nyrada was up 3.5 cents or 12.3 percent to 32 cents with 2.4 million shares traded.

NOXOPHARM

Noxopharm says the European Patent Office has granted a patent for the administration of Veyonda in cancer patients receiving chemotherapy or radiotherapy.
Noxopharm said that the patent, titled 'Isoflavonoid composition with improved pharmacokinetics', would protect its intellectual property until April 6, 2037.
The company said the patent covered the therapeutic use of idronoxil in a suppository dosage formulation intended to provide a steady-state blood level of drug.
Noxopharm was up four cents or 6.7 percent to 64 cents.

LIFESPOT HEALTH

Lifespot says shareholders will vote to issue 7,000,000 'in the money' options to directors Frank Cannavo, Rodney Hannington and Justyn Stedwell.
Lifespot said it proposed that Mr Cannavo and Mr Hannington receive 3,000,000 options each, with Mr Stedwell to receive 1,000,000 options, exercisable at eight cents each by June 30, 2023.
The company said the annual general meeting would vote on a conditional spill meeting following last year's 41.8 percent first strike remuneration report vote.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for re-election at a subsequent meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
Lifespot said that shareholders would vote to adopt the remuneration report, re-elect director Mr Hannington, ratify the prior issue of 4,000,000 shares, approve 13,100,000 shares issued in a placement facility and approve an additional capacity to issue shares.
The meeting will be held virtually on July 30, 2021 at 11am (AEST).
Lifespot was unchanged at 10 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a voluntary suspension to follow the trading halt requested on June 25 pending the release of a presentation to the American Diabetes Association (BD: Jun 25, 2021).
Proteomics said it hoped to lodge an announcement by July 2, 2021.
Proteomics last traded at 92.5 cents.

CRESO PHARMA

Creso has requested a voluntary suspension to follow the trading halt requested last week, pending an announcement on “sales and revenue update” (BD: Jun 25, 2021).
Today, Creso said the announcement was expected to be released by July 1, 2021.
Creso last traded at 14 cents.

EMYRIA

Emyria says it has appointed psychiatrist Dr Eli Kotler as the principal investigator for its MDMA-assisted psychotherapy trial for post-traumatic stress disorder.
Last month, Emyria said it has launched its ‘EMDMA-001’ psychedelic-assisted therapy program for treatment-resistant post-traumatic stress disorder (PTSD) with Mind Medicine Australia (BD: May 5, 2021).
Today, the company said the open-label EMDMA-001 trial with 3,4-methylene-dioxy-meth-amphetamine (MDMA), or Ecstasy, and psychotherapy would use MDMA and therapists to support patients with PTSD in a fit-for-purpose facility.
Emyria said Dr Kotler was the medical director of Melbourne’s Malvern Private Hospital and would be responsible for the conduct and delivery of the trial expected to begin by October 2021.
Emyria was up one cent or 5.7 percent to 18.5 cents with 1.5 million shares traded.