Biotech Daily

Tuesday June 15, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PATRYS UP 21%; ACTINOGEN DOWN 11%**

*** INVEX: US FDA, EMA DIFFER ON PRESENDIN IIH TRIAL ENDPOINTS**

*** KAZIA, CORNELL TRIAL PAXALISIB, KETOGENESIS FOR GLIOBLASTOMA**

*** OVENTUS RIGHTS RAISE $4.9m; TOTAL $10m**

*** COGSTATE $3.2m US PAYCHECK LOAN FORGIVEN**

*** NYRADA SELECTS NYR-BIO1 FOR TRAUMATIC BRAIN INJURY STUDY**

*** ANTERIS: ADAPT CAROTID ARTERY CONDUIT WORKS IN SHEEP**

*** RESPIRI WITHDRAWS $6m-$8m REVENUE GUIDANCE**

*** GENETIC TECHNOLOGIES US PATENT FOR GENOMIC ANALYSIS**

*** AZURE FOOD ADDITIVES NE1-ELITE, NE1-HEART READY FOR US SALE**

*** MGC: CANNEPIL ON IRISH REIMBURSEMENT SCHEME**

*** ZELIRA: HEALTH HOUSE MARIJUANA TOOTHPASTE UK DISTRIBUTOR**

*** AUSTRALIAN ETHICAL REDUCES TO 16% OF COGSTATE**

*** PYC US OFFICE AT J&J SAN DIEGO**

*** NEUREN APPOINTS CEO JON PILCHER MANAGING-DIRECTOR**

*** OPTHEA APPOINTS KAREN ADAMS CO SEC**

*** MGC LOSES CO SEC NADINE BARRY**

MARKET REPORT

The Australian stock market was up 0.92 percent on Tuesday June 15, 2021, with the ASX200 up 67.2 points to 7,379.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 19 fell and five traded unchanged. All three Big Caps were up.

Patrys was the best, up 0.7 cents or 20.6 percent to 4.1 cents, with 65.5 million shares traded. Kazia, Resmed and Telix climbed six percent or more; Alterity, LBT, Prescient and Universal Biosensors were up more than three percent; Pro Medicus rose 2.05 percent; Cochlear, CSL and Nanosonics were up more than one percent; with Avita, Clinuvel, Cynata, Medical Developments, Mesoblast, Orthocell and Polynovo up by less than one percent.

Actinogen led the falls, down two cents or 11.4 percent to 15.5 cents, with 16.35 million shares traded. Next Science lost 7.4 percent; Osprey was down 6.7 percent; Proteomics retreated 5.4 percent; Amplia, Immutep and Impedimed fell four percent or more; Optiscan and Starpharma were down more than three percent; Dimerix and Volpara shed more than two percent; Compumedics, Imugene, Opthea, Paradigm and Resonance retreated more than one percent; with Cyclopharm, Genetic Signatures and Neuren down by less than one percent.

INVEX THERAPEUTICS

Invex says the US Food and Drug Administration does not support intracranial pressure as a primary endpoint for its Presendin phase III idiopathic intracranial hypertension trial.
Invex said that in March, it submitted a phase III study protocol and statistical analysis plan as requested by the FDA, and sought its guidance on overall study design, particularly intracranial pressure and headache as key endpoints.
Today, the company said the FDA recommended it consider a "clinically meaningful effect on visual function" such as perimetric mean deviation, a measure of change in the patient's visual field, as the primary endpoint.
Invex said the FDA considered intracranial pressure (ICP) "an appropriate secondary endpoint of a study, but not a primary endpoint".
The company said the FDA had "very few specific comments" on its planned measure of monthly headache days and other headache measures but recommended an abbreviated headache severity scale as an alternative assessment.
Invex said the FDA advice "contrasts with that from the European Medicines Agency", which considered a lowering of ICP as an appropriate primary endpoint for a phase III study in idiopathic intracranial hypertension (IIH).
Invex chair Dr Jason Loveridge said that the clinical trial protocol and statistical analysis plan submitted to the FDA "sought to harmonize and gain a broad consensus between the EMA and FDA by incorporating assessments of headache and ICP as key endpoints - as recommended by EMA - which would best reflect both the signature of the disease and the very broad impact of headache on the quality of life of all IIH patients".
"In its response, the Division of Neurology repeated the original Division of Ophthalmology feedback that visual function should be a key outcome measure of a study seeking approval of a drug for the treatment of IIH in the US," Dr Loveridge said.
Invex said it intended to meet with its regulatory and clinical advisors to "better understand the type C meeting response from [the] FDA, and … to determine the best direction and design for a phase III study of Presendin in IIH".
Invex fell 11 cents or 16.8 percent to 54.5 cents with 1.8 million shares traded.

KAZIA THERAPEUTICS

Kazia says that with Cornell University it will conduct and initial 32-patient, phase II trial of its paxalisib in combination with a ketogenic diet for glioblastoma.
Kazia said the study would be conducted with New York City's Weill Medical College of the Ithaca, New York-based Cornell University.
The company said that cells generally relied on glucose for energy but when glucose was not available, cells could metabolize fats and proteins to provide energy, broken down to an intermediate form known as ketones.
Kazia said that unlike healthy cells, most tumor cells had difficulty metabolizing ketones and so a ketogenic diet might have potential for cancer treatment.
The company said the first arm of the phase II trial would enrol 16 patients with newly diagnosed glioblastoma who had unmethylated MGMT (oxygen-methylguanine-DNA methyltransferase) promotor status and resistant to temozolomide, while the second arm would enrol 16 patients with recurrent disease who had progressed after standard-of-care.
The company said both arms would combine paxalisib with metformin and a ketogenic diet and the initial 16-patient cohort would be expanded to about 30 patients if "there are signals of activity in a given arm".
Kazia said the study was expected to take two years.
Kazia was up nine cents or 6.9 percent to $1.40.

OVENTUS MEDICAL

Oventus says its fully underwritten one-for-4.4 rights offer at 12 cents a share has raised $4.96 million taking the total raised to $10.02 million.
Last month, Oventus said it had “firm commitments” to raise $5 million in a placement at 12 cents a share and expected to raise a further $5 million in an underwritten one-for-4.4 rights offer (BD: May 10, 2021).
Today, the company said it had applications for 14,892,320 shares, or 36.0 percent of the 41,326,998 shares available in the rights offer with the shortfall of 26,434,678 shares to be taken up by the underwriters Bell Potter Securities and Canaccord Genuity (Australia).
Oventus said that shareholders would receive one attaching option for every two new shares acquired, exercisable at 24 cents within two years.
Oventus was unchanged at 10.5 cents.

COGSTATE

Cogstate says the $US2.44 million ($A3.16 million) loan from Citibank has been forgiven under the Coronavirus Aid, Relief, and Economic Security (Cares) Act.
Last year, Cogstate said it received a $US2.44 million ($A3.79million) loan from Citibank under the US Federal Government Paycheck Protection Program (BD: May 6, 2020).
Today, the company said under the terms of the Cares Act it applied for forgiveness of loan used for US-based payroll costs, rent, utilities and other qualifying expenses.
Cogstate fell two cents or 1.4 percent to $1.37.

NYRADA

Nyrada says it has selected NYR-BIO1 for traumatic brain injury studies with the Silver Spring, Maryland-based Walter Reed Army Institute of Research.
Nyrada said NYR-BI01 was shown to be “a more potent and drug-like version of its predecessor NYX-1010” in a pharmaco-kinetic study to determine the level it penetrated the brain.
Nyrada chief executive officer James Bonnar said that the proposed compound for traumatic brain injury was able to cross the blood-brain-barrier “at above therapeutic levels … [meaning] our drug can reach the area of the brain damaged by traumatic brain injury”.
The company said the Walter Reed Army Institute of Research would use animal models of traumatic brain injury to mimic moderate to severe injury in humans, with testing to begin by October with results by the end of 2021.
Nyrada fell half a cent or 1.6 percent to 31 cents.

ANTERIS TECHNOLOGIES

Anteris says that its Adapt-treated bovine tissue carotid artery conduit shows no evidence of calcification in sheep.
Anteris said the conduits showed no visible signs of inflammation in the intimal or medial layers of the conduits.
The company said that the grafts used bovine carotid and mesenteric arteries as the conduits and showed the presence of “a partial neo-intimal layer, likely indicating surface remodelling of the vessels”.
Anteris said that based on the results, it planned a larger animal study in Australia this year implanting the conduit into the coronary artery bypass grafting position.
Anteris fell 19 cents or 2.5 percent to $7.51.

RESPIRI

Respiri says it has withdrawn its Wheezo revenue guidance of $6 million to $8 million by the end of this year due to the Covid-19 pandemic and related factors.

Last year, Respiri said that it expected revenue of between $6 million and $8 million from sales of its Wheezo asthma monitor and as software as a service for the year to December 31, 2021 (BD: Jul 27, 2020).

Today, the company said the Covid-19 pandemic had constrained direct sales and marketing activities by its Australian pharmacy partner Cipla Pty Ltd, which led to delays in activities including the 'Connected Care' nurse team and the number of pharmacies stocking Wheezo was slower than planned, along with reduced access to patient consulting rooms due to the pandemic.

"With the continued uncertainty around repeated state-based lockdowns and vaccination rates that will allow a return to ordinary business activity, the company has withdrawn its 2021 revenue guidance and does not consider it appropriate at this time to provide updated revenue guidance".

Respiri chief executive officer Marjan Mikel said that although the level of product inquiry was "pleasing, the impost on pharmacist's time and pharmacy banner groups caused by the pandemic has meant the company's key strategic initiatives to drive sales have experienced delays of approximately six months, which has impacted the signing of banner group agreements, pharmacy-level stocking, awareness, education and ultimately sales of Wheezo in the first five months of the year through to May 31, 2021".

"It is therefore unlikely the lost sales momentum can be restored during the remainder of the year for the Company to meet its guidance forecast," Mr Mikel said

Respiri, and previously Isonea and Karmelsonix, has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006).

Respiri fell one cent or 11.9 percent to 7.4 cents with 4.2 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has been granted a US patent relating to its human genomic analysis and identifying pharmaco-genomic markers.

Genetic Technologies said the patent was titled 'Computer Systems and Methods for Genomic Analysis'.

Genetic Technologies chief executive officer Simon Morriss told Biotech Daily the patent would protect its intellectual property until December 2024.

The company said that the patent application was "submitted in 2016 building on a patent family dating back to 2001".

Genetic Technologies said the patent described "efficient methods for identifying variations … in the human genome and relating those variations to the genetic basis of disease and drug response".

Last year, the company said it had been granted a US patent for its Genetype polygenic risk test for breast cancer (BD: Jun 22, 2020).

Today, Genetic Technologies said the new patent extended the protection of its portfolio beyond breast cancer and future products.

The company said the methods formed the basis of Genome-Wide Association Studies, which focused on identifying single nucleotide polymorphisms with drug response which were pharmaco-genomic or pharmaco-genetic markers.

Genetic Technologies was unchanged at 0.9 cents with 15.1 million shares traded.

AZURE HEALTH TECHNOLOGY (MERGED WITH INVICTUS, TRADING AS VGI)

Azure says its over-the-counter NE1-Elite for reduction of muscle soreness and NE1-Heart for heart health have been manufactured and are available for sale in the US.
In March, Azure said it had completed its first US manufacturing run for the food additives to supply sales in the US, Australia and China.
Today the company said the products had arrived at its Florida warehouse.
Azure managing-director Dr Glenn Tong said the delivery was “a major milestone”.
In April, Azure said its initial public offer raised $2,497,000, with the VGI Group investing $2,250,000 and “in recognition of the importance of the VGI Group” it would change its name to VGI Health Technology, pending approval (BD: Apr 20, 2021).
On the National (formerly Newcastle) Stock Exchange, Azure was untraded at 24 cents.

MGC PHARMACEUTICALS

MGC says its Cannepil marijuana-derived epilepsy product will be free of charge for patients prescribed the treatment in the Republic of Ireland.
MGC said Cannepil was added to the Primary Care Reimbursement Service as part of the Medicinal Cannabis Access Program and would be covered under the Health Service Executive’s service plan.
MGC was up 0.2 cents or 4.35 percent to 4.8 cents with 11.3 million shares traded.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says it has appointed the Perth-based Health House International to distribute its marijuana-based Sprinjene CBD toothpaste in the UK.
In 2019, the then Zelda appointed Health House to distribute its Hope medical marijuana products for autism spectrum disorder in Australia and the UK (BD: Nov 21, 2019).
Today, Zelira said that Health House was required to buy $US500,000 ($A648,300) of Sprinjene CBD in the first 12 months of the exclusive five-year distribution agreement.
In 2020, Zelira said Health and Natural Beauty USA Corp would manufacture the products, including the CBD toothpaste developed by Sprinjene chief executive officer and founder Dr Sayed Ibrahim, and the Piscataway, New Jersey-based Sprinjene gluten-free, cruelty-free, vegan, kosher and halal oral care products were manufactured by Health and Natural Beauty USA Corp, which was located at the same address (BD: Sep 8, 2020).
Today, Zelira said the distribution agreement expanded the availability of Sprinjene CBD toothpaste from the US to the UK.
Zelira said that two of its directors Jason Peterson and Harry Karelis were shareholders in Health House, together holding about 17.3 percent of shares on issue.
Zelira said it was unable to quantify the total revenue that could be generated from the distribution agreement.
Zelira was up 0.1 cents or 2.1 percent to 4.8 cents with 3.2 million shares traded.

COGSTATE

Australian Ethical Investment says it has reduced its substantial shareholding in Cogstate from 29,485,793 shares (17.33%) to 26,775,141 shares (15.66%).
The Sydney-based Australian Ethical Investment said that between August 31, 2020 and June 10, 2021 it bought and sold shares, with the single largest sale 1,480,000 shares for $1,994,703 or $1.35 a share.

PYC THERAPEUTICS

PYC says its US headquarters has moved to the Johnson & Johnson Innovation, Jlabs at San Diego, California.
PYC said the new location would house pre-clinical and clinical development, regulatory, manufacturing, business development and general corporate operations while its drug discovery and laboratory operations would remain in Perth.
PYC was unchanged at 17.5 cents.

NEUREN PHARMACEUTICALS

Neuren says it has appointed chief executive officer Jon Pilcher to its board as managing director, effective from June 14, 2021.
Neuren fell one cent or 0.8 percent to $1.30.

OPTHEA

Opthea says it has appointed Karen Adams as its head of finance and company secretary effective from June 12, 2021.
Opthea said Ms Adams had previously worked as Victor Smorgon Group chief financial officer, Nexvet Biopharma director of finance, as well as for Biota Holdings and Agva-Gavaert.
The company said Ms Adams held a Bachelor of Business from Melbourne's Swinburne University.
Opthea fell two cents or 1.4 percent to $1.415 with 765,593 shares traded.

MGC PHARMACEUTICALS

MGC says that following the appointment of David Lim as company secretary Nadine Barry has resigned as company secretary, effective from June 14, 2021.
The company said Ms Barry would continue as the company's corporate secretary.
Ms Barry's Linkedin profile said she previously worked as Chieftain Securities' corporate secretary and held a Bachelor of Arts from Perth's Notre Dame University.