Biotech Daily

Tuesday June 8, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 10%; PRESCIENT DOWN 18%**

*** COGSTATE EARNS $26m ON ESAI, BIOGEN FDA ALZHEIMER'S APPROVAL**

*** REDHILL OPAGANIB PHASE II/III COVID-19 STUDY ENROLLED**

*** IMMURON ACQUISITION SUSPENSION; ASX ACTIVITIES QUESTIONS**

*** IMMUTEP, CARDIFF WORK ON CHEAPER, ORAL CANCER DRUGS**

*** ALMIRALL CHALLENGES ACRUX GENERIC ACZONE**

*** RACE CONTRACTS TRIALOG FOR ISRAEL AML COMBINATION TRIAL**

*** CLARITY: DALLAS JOINS CU64-67 PAEDIATRIC NEUROBLASTOMA TRIAL**

*** VISIONEERING LOSES 10% CAPACITY, TOM DOOLEY; CONSOLIDATION**

*** CRESO, HALUCENEX EXPAND MUSHROOM PSYLOCIBIN PTSD TRIAL**

*** AVECHO: 'TPM INCREASES CANNABIDIOL ABSORPTION UP TO 5.4 TIMES'**

*** CELLMID SUPPLY, COLLABORATION AGREEMENT WITH PUMP HAIRCARE**

*** PYC 2nd DRUG CANDIDATE WORKS FOR ADAO, IN-VITRO**

MARKET REPORT

The Australian stock market was up 0.15 percent on Tuesday June 8, 2021, with the ASX200 up 10.7 points to 7,292.6 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 12 fell and six traded unchanged. All three Big Caps were up.

Patrys was the best, up 0.3 cents or 10 percent to 3.3 cents, with 23.8 million shares traded. Mesoblast climbed 8.8 percent; Alterity improved 7.1 percent; Uscom was up 6.25 percent; Actinogen, Oncosil, Pro Medicus, Starpharma and Universal Biosensors were up more than three percent; Amplia, Clinuvel, Compumedics and Genetic Signatures rose more than two percent; Avita, Cochlear, Cynata, Nanosonics, Neuren, Nova Eye and Opthea were up one percent or more; with CSL, Kazia, Polynovo, Resmed and Telix up by less than one percent.

Prescient led the falls, down three cents or 18.2 percent to 13.5 cents, with 15.9 million shares traded. Imugene retreated 13.5 percent; Antisense and Optiscan fell more than four percent; Dimerix, Immutep and Impedimed shed more than two percent; Cyclopharm, Next Science, Paradigm and Volpara were down more than one percent; with Proteomics down 0.9 percent.

COGSTATE

The US Food and Drug Administration approval of Biogen's aducanumab for Alzheimer's disease will earn Cogstate at least US$20 million ($A25.8 million) over five years.

Cogstate told the ASX that last year it entered into an agreement with Tokyo's Eisai Co to exclusively develop and distribute Cogstate digital cognitive assessment technologies in healthcare and other markets worldwide (BD: Oct 26, 2020).

Today, Cogstate said that Eisai received the FDA accelerated approval for aducanumab for Alzheimer's disease with its development partner, the Cambridge, Massachusetts-based Biogen Inc.

Separately, Biogen said the wholesale cost of an Aduhelm infusion once every four weeks, was $US4,312 based on the 75kg average weight of a US patient with mild cognitive impairment or mild dementia, and the yearly cost at the maintenance dose of 10mg/kg would be $US56,000.

There has been extensive media coverage of the FDA decision, which over-ruled an FDA committee unanimously rejecting the drug.

Last year, the FDA Oncologic Drugs Advisory Committee voted nine to one in favor of Mesoblast's Remestemcel-L for graft-versus-host disease, but the FDA over-ruled the committee and said it required a further trial (BD: Aug 14, Oct 2, 2020).

Today, Cogstate chief executive officer Brad O'Connor told Biotech Daily that there were several conditions attached to the payment of the $US20 million over years six to 10 of the 10-year agreement, but Eisai no longer had the right to terminate the agreement.

Mr O'Connor said there were several confidential conditions involved, but the FDA approval had ended the right to termination after year five.

Cogstate said that the agreement included $US15 million up front, minimum contractual royalty payments over years one to five of $US10 million and minimum royalty payments over years six to 10 of $US20 million.

The company said its agreement with Eisai specifically excluded the clinical trials market, where it continued to market its cognition tests independently.

Cogstate said that with Eisai it was progressing plans to launch digital brain health assessments, including both a direct-to-consumer self-check as well as a medical device, Cognigram, to aid healthcare professionals in clinical diagnosis decisions.

The company said that it was expected "that such digital cognitive assessments will play an important role in supporting the type of large-scale cognitive assessment that will be necessary in the launch of disease modifying therapies, such as Aduhelm".

Cogstate said that the FDA accelerated approval was granted based on data from clinical trials demonstrating the effect of Aduhelm on reducing amyloid beta plaques, a biomarker that is reasonably likely to predict clinical benefit, in this case a reduction in clinical decline.

Biotech Daily has been told that the approval of Biogen's Alzheimer's drug aducanumab, was "in spite of the apparent skepticism of some neuro-scientists [but] sent its shares soaring".

Cogstate said that the FDA had required Biogen to conduct a controlled trial to verify the clinical benefit of Aduhelm in patients with Alzheimer's disease, and if the trial fails to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

The company said that the approval by the FDA of Aduhelm was the first new treatment approved for Alzheimer's disease since 2003 and was "the first approved therapy that targets the fundamental pathophysiology of the disease".

Cogstate said that measurement of cognition was a critical component of a diagnosis of Alzheimer's disease.

Cogstate climbed 47.5 cents or 51.35 percent to $1.40 with 6.3 million shares traded.

REDHILL BIOPHARMA

Redhill says it has completed enrolment of 475 patients in its phase II/III study of orally opaganib for the treatment of severe Covid-19.

Redhill said the enrolment exceeded the planned 464 patients with the blinded, blended mortality rates encouraging compared to mortality rates from other large platform studies.

The company said that opaganib, also known as Yeliva and ABC294640, was given to patients hospitalized with severe Covid-19 pneumonia, with the primary endpoint "the proportion of patients breathing room air without oxygen support by day-14".

Last year, Redhill began trialing opaganib for Covid-19 with a compassionate use application to Israel and Italy in April, followed by a June application to the Russian Federation's Ministry of Health for a 270-patient phase II/III trial of opaganib for severe Covid-192 and pneumonia (BD: Apr 7, Jun 2021).

Also in April last year, the company said an investigational new drug application had been submitted to the US Food and Drug Administration to evaluate opaganib in a clinical study in 40 adults diagnosed with Covid-19 and pneumonia (BD: Apr 21, 2020).

Today, Redhill said the study captured additional outcome measures in the follow up period of up to six weeks, such as the time to hospital discharge, clinical improvement and incidence of intubation and mortality.

Redhill medical director Dr Mark Levitt said that enrollment completion was "a truly exciting milestone in the urgent search for an effective pill to treat Covid-19".

"Acting on the cause and effect of Covid-19 through a dual antiviral and anti-inflammatory effect, opaganib is host-targeted and is therefore expected to be effective against emerging viral variants," Dr Levitt said.

"With waves of Covid-19 continuing to wash over many countries, coupled with the specter of new variants, it is more critical than ever that the world has access to an oral pill to treat Covid-19," Dr Levitt said.

Redhill said opaganib was a new chemical entity, a first-in-class, oral, sphingosine kinase-2 (SK2) selective inhibitor, with dual anti-inflammatory and anti-viral activity.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill was up 28 US cents or four percent to $US7.35 ($A9.49) with 336,230 shares traded.

IMMURON

In May, Immuron has requested a trading halt pending an announcement "in connection to a planned acquisition" which was followed by a requested for a voluntary suspension was not expected to exceed five business days (BD: May 27, 31, 2021).

The company said on May 31, that the ASX was "requesting further information relating to the planned acquisition".

Today, Immuron said the ASX was considering a submission it has requested from the company in relation to ASX Listing Rule 11.1 and 11.2 and Guidance Note 12.

Listing Rules 11.1 and 11.2 and Guidance Note 12 refer to "significant changes of activities" including "proposed change to nature or scale of activities".

Since 2008, as the then Anadis, Immuron has been attempting to commercialize its cow colostrum-based treatments for a range of indications including traveller's diarrhoea, for which it is marketing the over-the-counter Travelan, as well as irritable bowel disease, fatty liver disease, non-alcoholic fatty liver disease, liver fibrosis, colitis, influenza, HIV, shigella, Clostridium difficile and Covid-19 (BD: Jul 22, 2008).

Immuron last traded at 16 cents.

IMMUTEP

Immutep says it is working with Cardiff University on a lower cost oral small molecule anti-LAG-3 therapies for cancer.
Immutep said the collaboration began in 2019 with Cardiff University's Prof Andrew Godkin and Prof Andrea Brancale.
Prof Godkin said his group was "delighted" to work with Immutep on the project to develop a small molecule anti-LAG-3 treatment for cancer patients could offer the convenience of a tablet or capsule, at a fraction of the cost of existing anti-LAG-3 candidates.
The company said that intellectual property relating to lead compounds as well as derivatives would be jointly owned by it and the University, and Immutep would have exclusive rights to develop and commercialize the new molecules.
Last year, Immutep said it won a $671,427 Australian Research Council Linkage grant with Monash University for a lymphocyte activation gene-3 (LAG-3) (BD: Aug 31, 2020).
Immutep said the collaboration with Monash University began in 2017 to investigate the structure of LAG-3 and how it bound to its main ligand, MHC class II.
Today, the company said the Monash University's research team was led by Prof Jamie Rossjohn, who was also a professor in structural immunology at Cardiff University.
Immutep fell 1.5 cents or 2.3 percent to 64 cents with 4.2 million shares traded.

ACRUX

Acrux says Almirall LLC has begun litigation in the US District Court of New Jersey, challenging its regulatory application for a generic version of Almirall's Aczone gel.
In April, Acrux said it had filed an abbreviated new drug application to the US Food and Drug Administration for dapsone gel 7.5%, a generic version of the Exton, Pennsylvania-based Almirall's Aczone gel 7.5% (BD: Apr 15, 2021).
Today, the company said that gel was an anti-acne treatment and the filing was under Paragraph IV asserting that the Almirall's patent number 9,517,219 was invalid, unenforceable and/or would not be infringed by Acrux's product.
Acrux said that Almirall asserted that US patent 9,517,219 was one of two patents listed in the FDA Orange Book for Aczone gel.
The company said in April that the Paragraph IV certification asserted that both listed patents were invalid, unenforceable and/or would not be infringed by its product.
Acrux said the action began patent litigation under the Hatch-Waxman Act.
Acrux fell 1.5 cents or 10.7 percent to 12.5 cents with 1.9 million shares traded.

RACE ONCOLOGY

Race says it has a contract with Israel's Trialog Clinical Trials to support its 29-patient, phase II, combination trial for acute myeloid leukaemia.
In May, Race said the trial would combine clofarabine and fludarabine with Bisantrene following pre-clinical studies that showed the three-drug combination had superior efficacy in targeting acute myeloid leukaemia cells (BD: May 10, 2021).
Today, the company said that Trialog would supply the trial drugs, including Bisantrene, as well as provide other clinical services to Race and Tel Aviv's Chaim Sheba Hospital.
Race said the trial had ethics approval and would be supervised by the Chaim Sheba's Prof Arnon Nagler, with the first patient expected to be treated by October 2021.
The company said that the supply agreement with Trialog had a maximum cost of $US801,247 ($A1,032,110) and would be invoiced in line with patient enrolment.
Race fell seven cents or 1.9 percent to $3.70 with 758,155 shares traded.

CLARITY PHARMACEUTICALS

Clarity says that adding the Dallas-based University of Texas Southwestern Medical Centre takes its paediatric neuroblastoma trial of copper Sartate to five clinical sites.
Last year, Clarity said it treated the first paediatric patient with 67Cu-Sartate, following a positive diagnostic scan with copper 64 (64Cu)-Sartate, in its 34-patient, phase I/II, dose-escalating, open label, non-randomized, diagnostic and therapy trial at New York's Memorial Sloan Kettering Cancer Centre (BD: Nov 3, 2020)
Today, the company said it had added the Cincinnati Children's Hospital Medical Centre, the Medical University of South Carolina, and the University of Wisconsin to its participating centres.
Clarity said it was recruiting patients in the study at all five sites.
Clarity is a public unlisted company.

VISIONEERING TECHNOLOGIES

Visioneering says that 606,357,088 votes (46.34%) defeated the 10 percent placement special resolution and director Tom Dooley has resigned, effective from June 7, 2021.
In its notice of meeting, Visioneering said that the placement capacity vote required a 75 percent majority, but the 701,467,131 votes (53.61%) in favor did not succeed.
The company said that the meeting approved the 100-to-one consolidation and the election of directors Jean Franchi and Andrew Silverberg were passed overwhelmingly.
Visioneering said it had 2,363,512,855 shares on issue, meaning the opposition to the placement capacity amounted to 25.65 percent of the company, sufficient to call extraordinary general meetings.
Visioneering was unchanged at 1.3 cents with 1.7 million shares traded.

CRESO PHARMA

Creso says that target company Halucenex Life Sciences will expand recruitment for its phase II trial of mushroom-derived psylocibin for post-traumatic stress disorder.
Creso said recruitment would include people who had not served in the military or worked as first responders, with treatment-resistant, post-traumatic stress disorder (PTSD).
The company said the expansion followed "the overwhelming amount of inbound enquiries … received from individuals that suffer from debilitating mental health conditions and are seeking alternative treatment methods".
Creso said that Halucenex expected to begin the phase II trial following the receipt of a Dealer's Licence from Health Canada.
Creso fell half a cent or 3.1 percent to 15.5 cents with 17.7 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says that its tocopheryl phosphate mixture (TPM) phosphorylated vitamin E can "increase the dermal absorption of [cannabidiol] by 3.2 to 5.4 times".
The company said that chief executive officer Dr Paul Gavin would present the data at the virtual 'Global Cannabis Intelligence Summit 2021' in a presentation titled 'Overcoming cannabinoid formulation challenges using TPM, a novel form of Vitamin E'.
Avecho said that TPM increased both the oral and dermal absorption of cannabinoids Dr Gavin said that topical cannabinoid formulations were "receiving attention for a range of clinical indications, including dermatology and pain".
Avecho was unchanged at 1.8 cents.

CELLMID

Cellmid says it has a supply agreement with Pump Haircare Pty Ltd for its FGF5 inhibitor hair growth products under the Pump brand and to work on new products.
Cellmid said the agreement was through its consumer health subsidiary, Advangen International Pty Ltd, which would manufacture and supply the Sydney-based Pump-branded hair lotions using its FGF5 inhibitor hair loss prevention and hair growth technology.
The company said that Pump would cover all marketing activities and sell the hair lotions.
Cellmid said the two companies would also collaborate on new products.
Cellmid fell 0.2 cents or three percent to 6.4 cents with 1.5 million shares traded.

PYC THERAPEUTICS

PYC says in-vitro studies show that its second drug candidate for autosomal dominant optic atrophy “rescues the critical functional deficit that causes blindness in patients”.
PYC said that the unnamed drug candidate prevented the cell death that causes blindness in patients with autosomal dominant optic atrophy (ADOA).
The company said the unnamed drug candidate had “potential application in patient subgroups in other diseases with underlying mitochondrial dysfunction including glaucoma, Parkinson’s disease and Alzheimer’s disease.
PYC chief scientific officer, Prof Sue Fletcher said that “if the cell survival and functional benefits that we see in patient-derived models treated with this drug candidate are replicated in the clinic, this has the potential to change the lives of ADOA patients in a very meaningful way”.
PYC fell one cent or 5.4 percent to 17.5 cents with 3.7 million shares traded.