Biotech Daily

Wednesday December 18, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRESCIENT UP 8%; PHARMAXIS DOWN 40%**

*** BOERHINGER INGELHEIM ENDS PHARMAXIS BI1467335 FOR NASH**

*** DMC: MESOBLAST REVASCOR HEART FAILURE TRIAL CONTINUES**

*** FEDERAL $9m FOR 24 CANCER RESEARCH PROJECTS**

*** REDHILL US LAUNCH OF AEMCOLO FOR TRAVELLER'S DIARRHOEA**

*** REGENEUS RECEIVES $50k INNOVATION CONNECTIONS GRANT**

*** GENETIC TECHNOLOGIES UP-TO $15m US SEC REGISTRATION**

*** PALLA ENDS KARO NON-OPIATE DEAL FOR CODEINE**

*** AUSCANN COMPLETES TESTING OF MARIJUANA CAPSULES**

*** ELIXINOL TO RELEASE 78m ASX ESCROW SHARES**

*** MGC REMOVED FROM BNY MELLON PERSHING LIST**

*** ELIXINOL LOSES EXECUTIVE PAUL BENHAIM, CONTINUES AS DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Wednesday December 18, 2019, with the ASX200 up 4.1 points to 6,851.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and three were untraded. All Big Caps rose.

Prescient was the best, up 0.6 cents or 7.6 percent to 8.5 cents, with 7.5 million shares traded. Clinuvel climbed six percent; Polynovo improved 4.2 percent; Avita, Dimerix, Genetic Signatures and Medical Developments were up more than three percent; Pro Medicus and Telix rose two percent or more; Cochlear and Mesoblast were up more than one percent; with CSL, Neuren, Next Science and Resmed up by less than one percent.

Pharmaxis led the falls, down as much as 42.3 percent to 15 cents, before closing down 10.5 cents or 40.4 percent at 15.5 cents with 8.9 million shares traded. Kazia and Osprey lost more than six percent; Actinogen, Immutep, Impedimed, Paradigm and Patrys fell five percent or more, Antisense and Resonance were down more than four percent; Imugene and Oncosil lost more than three percent; Nanosonics, Opthea, Starpharma and Universal Biosensors shed more than two percent; Compumedics and Orthocell were down more than one percent; with Volpara down 0.8 percent.

PHARMAXIS

Pharmaxis says Boehringer Ingelheim has terminated the BI1467335 (PXS4728A) program for non-alcoholic steatohepatitis, acquired in 2015.

In 2015, Pharmaxis said it sold PXS4728A, renamed BI1467335, to the Ingelheim, -based Boehringer Ingelheim for an upfront fee of $39.2 million and up to $750 million in milestone payments (BD: May 18, 2015).

Today, the company said the second BI1467335 program for diabetic retinopathy would continue.

Pharmaxis chief financial officer David McGarvey told Biotech Daily that “of the remaining $600 million (EUR362 million) milestones, Pharmaxis has lost the potential for a further EUR185 million but retains the potential for a further EUR177 million with high single digit royalties and sales milestones”.

Pharmaxis said that a 12-week, multi-centre, double-blind, 114-patient phase IIa safety and efficacy trial for non-alcoholic steatohepatitis (NASH) was found to be well tolerated, with no serious adverse events, but Boehringer Ingelheim decided not to further develop BI1467335 for NASH due to the “risk of drug interactions of the compound in NASH patients”.

The company said patients were randomized into one of four dosages of BI1467335 or a placebo for 12 weeks and it found that the drug met pre-specified targets for inhibition of plasma amine oxidase copper-containing-3 (AOC3) activity compared to a placebo and showed clinically relevant changes in NASH biomarkers.

Pharmaxis said Pharmaxis chief executive officer Gary Phillips said the company was “disappointed that BI1467335 is not advancing in NASH”.

“We look forward to further scientific discussion when the full data and analysis from this phase IIa clinical trial and Boehringer Ingelheim’s recently reported phase I study are available for review,” Mr Phillips said.

Pharmaxis said that Boehringer Ingelheim had completed recruitment for a phase IIa study of BI1467335 for diabetic retinopathy, due to report by the end of 2020, which remained unaffected by the decision.

The company said it closed the September quarter with $23 million in cash and in October, received a $6.2 million Research and Development Tax Incentive.

Pharmaxis said that it expected a $US10 million ($A14.6 million) milestone payment from its US licencee Chiesi for Bronchitol by October 2020, subject to US Food and Drug Administration approval in mid-2020.

Pharmaxis said the funds were sufficient to progress two programs: its anti-fibrotic lysyl oxidase (LOX) inhibitor program and its pan-LOX inhibitor program, which was expected to report the results of a phase I safety study in healthy volunteers by April 2020.

Pharmaxis fell as much as 11 cents or 42.3 percent to 15 cents, before closing down 10.5 cents or 40.4 percent at 15.5 cents with 8.9 million shares traded.

MESOBLAST

Mesoblast says the independent data monitoring committee has recommended that its phase III trial of Revascor for advanced chronic heart failure continue as planned.

Mesoblast said this was the 10th and final scheduled meeting with the DMC.

Yesterday, the company said it was conducting final visits in its 566-patient, double-blind, randomized, controlled phase III trial of Revascor for advanced chronic heart failure and had met more than 531 primary endpoint events, with results expected by mid-2020 (BD: Dec 17, 2019).

Mesoblast fell two cents or one percent to $1.94 with 1.8 million shares traded.

FEDERAL GOVERNMENT

The Federal Government says $7 million from the Government and $1.9 million from charities will fund 24 Australian cancer research projects.
A media release from Acting Federal Health Minister Anne Ruston said the projects would "focus on primary prevention cancer, and new and more effective treatments for cancers" including breast, endometrial, colorectal, lung, pancreatic, prostate, ovarian, head and neck cancer, multiple myeloma, melanoma and leukaemia.
The Government said the projects included six projects for childhood cancers with low survival rates, a new treatment for colorectal cancer, tumor-targeting nanoparticles to deliver gene-silencing drugs, the identification of the causes of familial breast cancer, surface guidance technology for head and neck cancer patients to reduce anxiety and stress in radiotherapy, and a blood test to identify patients for an immunotherapy treatment for cancer.
Ms Ruston said the investment was "critical in supporting the fight against some of the nation's worst diseases".
Details of successful grant applications are at: www.canceraustralia.gov.au.

REDHILL BIOPHARMA

Redhill says it has begun promoting rifamycin or Aemcolo in the US for Traveller's diarrhoea caused by non-invasive strains of Escherichia coli (E coli) in adults.
Redhill said Aemcolo was approved by the US Food and Drug Administration for the treatment of Traveller's diarrhoea and was covered by a US patent until the end of 2028.
In 2010, Israel's Redhill bought Myconda (RHB-104), Heliconda (RHB-105, Talicia) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Redhill chief operating officer Rick Scruggs said the company would expand its sales team to 140 staff to launch Aemcolo and Talicia for the Helicobacter pylori infection.
On the Nasdaq last night, Redhill fell 13 US cents (19 Australian cents) or 2.15 percent to $US5.92 ($A8.65) with 140,679 shares traded.

REGENEUS

Regeneus says it has received a $50,000 Innovation Connections Grant from the Federal Government's Department of Industry, Innovation and Science.
Regeneus said it was awarded the grant for its mesenchymal stem cell pain management study with Melbourne's Monash University.
The company said the funding matched its project spending over four months.
Regeneus was untraded at eight cents.

GENETIC TECHNOLOGIES

Genetic Technologies has filed a registration statement to the US Securities and Exchange Commission for a potential $US10 million ($A14.6 million) raising.
Genetic Technologies said the raising would be through the issue of American depositary shares (ASDs) with each ADS representing 600 Australian shares.
The company did not provide details of the price or when the raising would occur.
Genetic Technologies was unchanged at 0.5 cents with 4.2 million shares traded.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES)

Palla says it has “negotiated an early exit of a legacy manufacturing agreement with an non-opiate contract manufacturing organization Karo Pharma by February 2020.
Palla said the supply agreement was inherited as part of the acquisition of Palla Pharma’s downstream Norway operations in October 2017 and was due to run until June 2020.
The company said that the early termination released about $3 million of working capital used as safety stock and allows it to pursue more profitable opioid-based tablet manufacturing contracts, freeing up more than one billion tablets of tableting capacity which could generate additional revenue from higher margin opiate-based tablets.
Palla chief executive officer Jarrod Ritchie that “changes like this allow us to free up production to harness our competitive advantage as the lowest-cost, high-quality, vertically-integrated [narcotic raw material] producer servicing the world’s legal narcotics market”.
“It also allows Palla to explore more favorable contracts with opioid-based products on healthier margins,” Mr Ritchie said.
“The bespoke nature of the legacy [contract manufacturing organization] contract acquired in the acquisition and the range of extensive requirements needed to meet customer obligations had an adverse financial impact on Norway operations and overall profit margins,” Mr Ritchie said.
“The early termination allows Palla to reduce direct labor costs associated with the Norway plant and improve manufacturing efficiencies,” Mr Ritchie said.
Palla said it had entered into a new contract with the same customer to continue to provide its codeine phosphate-based tablets on favorable terms for a further period of two years.
Palla fell two cents or 1.9 percent to $1.03.

AUSCANN GROUP

Auscann says it has completed manufacturing and testing of its hard-shell capsules for marijuana medicines and has released a commercial sized batch for clinical evaluation.
Auscann said the capsules were tested to ensure product quality and were found to meet all applicable pre-defined criteria.
The company said the clinical evaluation would provide key exposure information to inform dose selection and would validate it as a commercial producer of reliable, stable and standardized pharmaceutical products.
Auscann said it would progress to commercialization and would supply products to physicians for availability to patients by July 2020.
Auscann chief executive officer Ido Kanyon said the release of the capsules was “an important milestone on the company’s accelerated road to sales”.
Auscann was up nine cents or 50 percent to 27 cents with 12.8 million shares traded.

ELIXINOL GLOBAL

Elixinol says that 77,870,572 ASX escrow shares will be released on January 8, 2020.
Elixinol said that after the release of the above securities there would be no securities subject to ASX restrictions.
According to the company’s most recent Appendix 3B new share issue announcement, after the release it would have 137,894,112 shares available for trading
Elixinol fell 6.5 cents or 8.5 percent to 70 cents.

MGC PHARMACEUTICALS

MGC says it has been removed from the Bank of New York Mellon's Pershing Securities restricted list for Australian marijuana companies.
MGC was unchanged at 3.1 cents with five million shares traded.

ELIXINOL GLOBAL

Elixinol says that founder, former chief executive officer and chief innovation officer, Paul Benhaim, has resigned for personal reasons, effective immediately.
Elixinol said that Mr Benhaim would continue as a non-executive director.
Mr Benhaim said his trust held 54,623,008 shares in ASX escrow which would be released on January 8, 2020.
Mr Benhaim said that he would not sell more than 10 percent of his holding for six months following the release from escrow and no more than 10 percent in the following six months.
Elixinol chairman Andrew Duff said the board thanked Mr Benhaim "for his important and long-standing contribution to Elixinol since its inception".
"We look forward to continuing to benefit from Paul's deep industry experience in his new role as non-executive director," Mr Duff said.