Biotech Daily

Thursday July 2, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: POLYNOVO UP 22%, USCOM DOWN 18%**

*** CLINUVEL: 'SCENESSE DRAMATICALLY CHANGES LIVES'**

*** FDA ALLOWS POLYNOVO BTM WOUND NEW DATA EXTENSION**

*** PHYLOGICA $10m UNDERWRITTEN 1-FOR-1 RIGHTS ISSUE**

*** IMUGENE HIRES SIMBEC-ORION FOR HER-VAXX GUT CANCER TRIAL**

*** ANALYTICA APPOINTS CURRENT TECHNOLOGY US DISTRIBUTOR**

*** IMMURON PHASE II IMM-124E NASH TRIAL 27.5% ENROLLED**

*** MEDIOBIO APPLIES FOR US PATENT FOR HEART STRESS TEST**

*** ORBIMED DROPS UNILIFE $26m DEPT HURDLE**

*** PHYTOTECH, MMJ MERGER UNCONDITIONAL**

*** FIL TAKES 6% OF STARPHARMA**

MARKET REPORT

The Australian stock market climbed 1.52 percent on Thursday July 2, 2015 with the ASX200 up 84.1 points to 5,599.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and eight were untraded.

Polynovo was the best, up two cents or 22.2 percent to 11 cents with 397,300 shares traded.

Analytica climbed 8.3 percent; Optiscan was up 7.7 percent; Neuren and Starpharma rose more than five percent; Universal Biosensors was up 3.4 percent; Acrux, Benitec, Medical Developments, Mesoblast and Nanosonics were up more than two percent; with Cochlear, CSL and Impedimed up more than one percent.

Uscom led the falls, down 3.5 cents or 18.4 percent to 15.5 cents with 118,641 shares traded. Ellex lost 9.1 percent; Genetic Technologies fell 6.45 percent; Avita was down five percent; Living Cell and Prima fell four percent or more; Biotron was down 3.6 percent; Circadian, Psivida and Viralytics shed more than two percent; Resmed was down 1.4 percent; with Sirtex down 0.4 percent.

CLINUVEL

Clinuvel says that a journal article combining two of its trials concludes that Scenesse dramatically changes the lives of erythropoietic protoporphyria patients.

Clinuvel said that the article, entitled 'Afamelanotide for Erythropoietic Protoporphyria' was published in the New England Journal of Medicine and reviewed results from 168 patients in two phase III studies, CUV029 in Europe and CUV039 in the US.

The company said the combined analyses showed that those who received Scenesse, or afamelanotide 16mg, could expose their skin to daylight and sun without incurring characteristic phototoxic burns, with statistically significant longer exposure seen in patients who received the active drug ($p = 0.04$ in the US and $p = 0.005$ in Europe).

Clinuvel said that the Scenesse group showing marked improvement of quality of life at various time points compared to placebo ($p < 0.001$ to $p = 0.06$).

The abstract is at: http://www.nejm.org/doi/full/10.1056/NEJMoa1411481 and concluded that "afamelanotide had an acceptable side-effect and adverse-event profile and was associated with an increased duration of sun exposure without pain and improved quality of life in patients with erythropoietic protoporphyria".

Clinuvel said that the authors "emphasized difficulties" of evaluating a novel treatment for a disease not previously subjected to parallel placebo-controlled randomised clinical trials.

The company said that erythropoietic protoporphyria was a particularly complex genetic disorder, with patients experiencing intense fear of incurring phototoxicity due to light exposure and severe dermal burns could result from any exposure to light, resulting in prolonged distress and incapacitation.

Netherlands Porphyria Centre internal medicine professor and co-author Prof Paul Wilson said that "the effect of afamelanotide on diminishing these restrictions and on patient quality of life is dramatic".

"Even more dramatic than has been captured by the trial assessment tools and a great advantage of the drug is that side effects are minimal," Prof Wilson said.

"The approval of afamelanotide by the European Commission following these trial results represents a major breakthrough," Prof Wilson said.

Clinuvel was untraded at $2.84.

POLYNOVO

Polynovo says the US Food and Drug Administration has allowed an extension for new data for its 510k biodegradable temporising matrix wound treatment application.

Yesterday, Polynovo said that an article entitled 'Free flap donor site reconstruction: A prospective case series using an optimized polyurethane Biodegradable Temporising Matrix (BTM)' had been published by Eplasty, a peer-reviewed open-access journal, and it was available at: http://bit.ly/1elklLq with the authors reporting that the Novosorb polymer had "almost completely biodegraded, resulting in a neo-dermal skin structure replacing the polymer in every patient … and split-skin graft take [or success] rate was 100 percent".

Polynovo said that no infections were observed.

Polynovo said that its new regulatory team considered the data in the original submission could be enhanced with the recent clinical publications and greater detail of the histological progress of patients.

The company said that FDA had agreed to extend the due date by 180 days, but it was "confident [it] will complete the dossier sooner than their allocated time".

Polynovo chief executive officer Paul Brennan said that "whilst no one likes a delay in the 510(k) application we consider it prudent to look at the near and long term objectives of having a robust and detailed data set supporting our product and our clinicians".

Polynovo was up two cents or 22.2 percent to 11 cents.

PHYLOGICA

Phylogica says it will raise up to $10,020,694 in a fully-underwritten one-for-one entitlement issue at one cent a share.
Phylogica said that Patersons Securities had fully underwritten the offer and sub-underwriting was “mostly from existing major shareholders”.
The company said that the proceeds would be used to advance its cancer programs towards the clinical development stage.
Phylogica said that the record date for the offer was July 9, the offer would open on July 14 and close on July 23, 2015.
Phylogica fell one cent or 43.5 percent to 1.3 cents with 16.9 million shares traded.

IMUGENE

Imugene says it has appointed Simbec-Orion Group to conduct its phase Ib/II trial of HER-Vaxx for metastatic gastro-oesophageal adenocarcinoma.
Imugene said that the Merthyr Tydfil, Wales-based contract research organization would plan and manage the clinical trials including identifying optimal hospitals and investigators experienced in immuno-oncology for the HER-Vaxx immunotherapy trial, which was due to begin by the end of 2015.
The company said that the trial was entitled ‘A Phase Ib/II, Randomized, Double-Blind, Placebo-Controlled Comparison of IMU-131 (HER-Vaxx) HER2/neu Peptide Vaccine Plus Cisplatin and either Capecitabine or 5-Fluorouracil Chemotherapy in Patients with HER2/neu Overexpressing Metastatic or Advanced Adenocarcinoma of the Stomach or Gastroesophageal Junction’.
Imugene managing director Charlie Walker said that the selection of a contract research organization was “another milestone”.
“Our trial is designed to be statistically robust and also yield early significant data … and has been designed to appeal to potential partners and help steer the phase III clinical trial design,” Mr Walker said.
Imugene was unchanged at 1.1 cents.

ANALYTICA

Analytica says it has appointed the Minneapolis, Minnesota-based Current Technology as a non-exclusive Pericoach distributor in the US.
Analytica said that Current Technology would buy wholesale quantities of the intra-vaginal Pericoach pelvic floor diagnostic and training system and engage in marketing and sales activities through its sales network.
The company said that additional sales channel would enhance its own US based distribution, but it would retain customer registration and maintenance of patient training records data
Analytica said that Current Technology was a specialized distributor to physical therapists and medical practitioners in the pelvic rehabilitation market for more than 20 years.
Current Technology founder and president Rod Pitsch said that the Pericoach system was “a natural product line extension to offer our clinical partners and women they serve”.
“The technology and ease of the Pericoach with the benefit of real-time biofeedback I believe will be a great benefit to women,” Mr Pitsch said.
Analytica was up 0.1 cents or 8.3 percent to 1.3 cents with 2.3 million shares traded.

IMMURON

Immuron says that it has enrolled 33 of the 120 patients in its phase II trial of IMM-124E for non-alcoholic steatohepatitis.
Immuron said that 10 more patients had been recruited and were progressing to dosing, with 13 US sites and six Australian sites initiated and more to be added in the US and Israel.
The company began the randomized, double-blind, placebo-controlled phase II study last year (BD: Nov 27, 2014).
Today, Immuron said that patients were being randomized to be administered either 600mg or 1,200mg oral doses of IMM-124E or placebo three times daily for six months.
The company said that the primary objectives of the study were to evaluate the safety and preliminary efficacy of IMM-124E.
Immuron said that non-alcoholic steatohepatitis was a progressive form of non-alcoholic fatty liver disease, characterized by fat build-up in the liver, or steatosis, and chronic inflammation and might progress to cirrhosis, liver failure and cancer.
Immuron said that its prevalence was increasing and was associated with rising obesity, dyslipidemia and type 2 diabetes.
The company said it expected to have the trial fully recruited by the end of 2015.
Immuron fell two cents or eight percent to 23 cents.

MEDIBIO

Medibio says it has applied to the US Patent Office for a provisional patent covering its cardiac test to measure the level of stress and its health and wellbeing impact.
Medibio said the application was entitled ‘Method and System for Monitoring Stress Conditions’ and would complement the existing patents covering its cardiac rhythm mental health diagnosis.
The company said it intended to seek patent protection in major jurisdictions including, but not limited to, Australia, the US, the UK, EU, Japan, China, and Russia.
Medibio said the patent application specifically covered the use of circadian heart rate technology to assess the level and impact of stress, measuring the type and degree of deviation of the subject’s circadian heart rate from normal and “used the diagnostic significance of this to accurately classify individuals into one of three categories based on the impact stress has had on their health and wellbeing”.
The company said it was advancing patent applications related to mental health diagnosis.
Medibio chief executive officer Kris Knauer said the company had “disruptive technology related to the diagnosis of mental health disorders and the assessment of stress and we need to put as much exclusivity around this key asset as possible”.
Medibio was up one cent or 3.3 percent to 31 cents.

UNILIFE CORPORATION

Unilife says its Orbimed agreement has been amended removing a requirement to generate $US20 million ($26.2 million) in cash in the six months to June 30, 2015.
Unilife said there were no other changes to the agreement as part of this amendment.
Last year, Unilife said it has a $US60 million debt financing agreement with the New York-based Orbimed (BD: Mar 14, 2015).
The company said it recorded $US5.5 million and $US14.4 million in unaudited cash receipts for the three and six month periods to June 30, 2015, respectively.
Unilife fell one cent or 2.15 percent to 45.5 cents.

PHYTOTECH

Phytotech says the conditions for its merger with MMJ Bioscience have been met and details of the settlement are expected “within the coming days”.

In May, Phytotech said it would vote to merge with MMJ, change its name to MMJ Phytotech and grant 7,000,000 rights 9,850,000 options to executives and directors (BD: May 26, 2015).

All resolutions to the meeting were passed overwhelmingly, with the closest vote the issue of performance rights which was supported by 771,393 votes and opposed by 89,480 votes.

The company meeting results notice said that all resolutions were opposed by 89,480 votes, with 15 of 16 resolutions supported by more than 2,253,793 votes.

Phytotech was up two cents or 6.7 percent to 32 cents.

STARPHARMA

The Sydney and Hong Kong-based FIL Limited says it has increased its substantial holding in Starpharma from 16,106,957 shares (5.05%) to 19,654,406 shares (6.16%).

FIL said it acquired the shares between June 9 and 26, 2015 at prices ranging from 72 cents to 78 cents.

Starpharma was up four cents or 5.6 percent to 76 cents.