Biotech Daily

Monday December 11, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRANA UP 10%; LBT DOWN 4%**

*** MELBOURNE UNI, IBM COLLABORATE TO PREDICT EPILEPTIC SEIZURES**

*** PATRYS: 'PAT-DX1, OLAPARIB SYNERGISTIC FOR CANCER IN-VITRO'**

*** ZELDA, PHILADELPHIA CHILDREN'S MARIJUANA AUTISM STUDY**

*** CSL RENEWS NATIONAL BLOOD AUTHORITY SUPPLY AGREEMENT**

*** ITL LAUNCHES SEGMENT SAMPLER FOR LAB BLOOD SAMPLING**

*** PRESCIENT RESUMES PTX-200 FOR BREAST CANCER RECRUITMENT**

*** BIOXYNE: 'EARLY DATA BACKS PROBIOTIC PROGASTRIM FOR GUT HEALTH'**

*** ADMEDUS MOVES FINANCIAL YEAR TO DEC 31, NEXT AGM MAY 2018**

*** ORTHOCELL REQUESTS CAPITAL RAISING TRADING HALT**

*** OVENTUS REQUESTS CAPITAL RAISING TRADING HALT**

*** MMJ REQUESTS 'MATERIAL INVESTMENT' TRADING HALT**

*** HYDROPONICS TO RELEASE 14.7m ESCROW SHARES**

*** REGENEUS APPOINTS JAPAN-BASED LEO LEE DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Monday December 11, 2017 with the ASX200 up 3.9 points to 5,998.3 points. Eighteen of the Biotech Daily Top 40 stocks were up, nine fell, nine traded unchanged and four were untraded.

Prana was the best, up 0.7 cents or 10.3 percent to 7.5 cents with 200,305 shares traded. Osprey and Pro Medicus climbed more than five percent; Medical Developments was up 4.3 percent; Volpara improved 3.3 percent; Benitec, Mesoblast and Neuren rose more than two percent; Admedus, Bionomics, Ellex, Nanosonics, Optiscan, Pharmaxis, Polynovo and Sirtex were up more than one percent; with Airxpanders, Resmed and Viralytics up by less than one percent.

LBT led the falls, down one cent or 4.4 percent to 21.5 cents with 933,589 shares traded. Dimerix fell four percent; Acrux, Impedimed, Oncosil and Universal Biosensors were down more than three percent; Opthea shed two percent; Avita and Starpharma lost more than one percent; with Cochlear and CSL down by less than one percent.

THE UNIVERSITY OF MELBOURNE, IBM RESEARCH AUSTRALIA

A collaboration between the University of Melbourne and IBM Research Australia is developing a tool to predict epilepsy seizures.

A media release from the University of Melbourne said that using a mobile processor to analyse brain signals from retrospective patient data, the device predicted an average of 69 percent of seizures across all patients.

The University said that the teams used “the world’s most comprehensive epilepsy patient [electro-encephalogram] dataset collected from electrodes inside patients’ skulls”.

The head of the University’s Department of Biomedical Engineering Prof David Grayden said the technology had the ability to adapt to individual patient’s needs.

“By collecting data from inside the patient’s skull and combining this with deep learning and [artificial intelligence], we’re able to develop a system that can self-train, based on learning the brain states and signs that pre-empt seizures unique to an individual,” Prof Grayden said.

“Our algorithm also allows for instantaneous and easy adjustment, giving patients the flexibility to control how sensitive and in advance the warning is,” Prof Grayden said.

IBM Research-Australia’s Dr Stefan Harrer said that previous epilepsy prediction research was only possible on high powered computers.

Dr Harrer said that by using IBM’s “brain-inspired computing chip, there is the potential to create a wearable, real-time patient warning system”.

“By deploying the technology on a computing chip that is the size of a postage stamp and runs on the same power use of a hearing aid, we’re able to simulate how such systems could one day operate in real life,” Dr Harrer said.

“The hope is that one day this research could help inform the development of assistive technologies that could not only warn people with epilepsy of imminent seizures, but constantly adapt to how their brains change over time,” Dr Harrer said.

The research article, entitled ‘Epileptic Seizure Prediction using Big Data and Deep Learning: Toward a Mobile System’ is expected to be published in the Lancet journal Ebiomedicine.

At the time of publication a link to the article or the abstract was not available.

The director of the University of Melbourne’s Graeme Clark Institute for Biomedical Engineering and director of neurology at Melbourne’s St Vincent’s Hospital Prof Mark Cook said that one third of epilepsy patients lived with unpredictable seizures that were not adequately controlled.

Prof Cook said that the research “could dramatically improve the lives of 250,000 Australians and 65 million people worldwide”.

“Epilepsy is a neurologic condition that can be incredibly debilitating,” Prof Cook said.

“It prevents some patients from doing simple activities such as getting a driver’s licence or swimming,” Prof Cook said.

“This technology has the potential to improve millions of lives and reduce the physical, emotional, and financial costs of one of the world’s most common, yet intractable chronic disorders,” Prof Cook said.

Prof Cook said developing a reliable means of predicting epileptic seizures for individual patients was “an incredibly complex area of research”.

“This is in large part due to how epilepsy manifests itself uniquely in each patient, as well as individual long-term changes in brain signals,” Prof Cook said.

“While we still need to continue to build on this research before we can confidently say that we can identify any seizure before it occurs, these results have proven incredibly promising,” Prof Cook said.

PATRYS

Patrys says that in-vitro experiments show that PAT-DX1 acts synergistically with olaparib, the first approved poly-adenosine diphosphate-ribose-polymerase (PARP) inhibitor.
Patrys said that the olaparib, marketed by Astrazeneca as Lynparza, was a targeted therapy for cancer, approved in both the US and Europe.
The company said that olaparib interfered with DNA repair and acted against cancers with defects in homologous recombination due to BRCA1 or BRCA2 mutations, including some ovarian, breast, and prostate cancers.
Patrys said that olaparib was the first PARP inhibitor approved for use in humans and numerous other PARP inhibitors were in clinical trials, particularly because of their toxicity against cancer cells with impaired DNA repair mechanisms.
The company said that a study comparing PAT-DX1 with olaparib at Yale University found that both molecules killed a range of different cancer cells as single agents and when used simultaneously their combined action was synergistic rather than additive, supporting the understanding that they acted through different but complementary pathways.
Patrys said that combinations of PAT-DX1 and olaparib were tested on brain and colon cancer cells with defective DNA repair pathways and in both PAT-DX1 and olaparib alone were toxic to the cells in a dose responsive manner, but in combination they synergized to significantly increase cancer cell death compared to either agent alone.
The company said that cells with intact DNA repair were not killed by PAT-DX1, olaparib, or the combination and the findings indicated the potential for combinations of PAT-DX1 and PARP inhibitors to have an increased impact on DNA repair-deficient tumors while sparing normal tissue.
Patrys said PAT-DX1 was a humanized version of deoxymab 3E10, an antibody that interrupted cells' DNA damage repair mechanisms, specifically inhibiting multiple DNA repair pathways, including base excision repair and homologous recombination, and it had previously shown positive results in a range of different pre-clinical models of cancer including glioblastoma, colon cancer and triple negative breast cancer.
Patrys chief executive officer Dr James Campbell said that the discovery that PAT-DX1 worked synergistically with a PARP inhibitor "confirms the leading position that Patrys is establishing in the field of DNA damage response therapeutics".
"Patrys will expand on this study with various animal models and with PAT-DX1-conjugated nanoparticles dosed with olaparib," Dr Campbell said.
"Positive results from these studies will significantly strengthen the potential and attractiveness of the Deoxymab platform," Dr Campbell said.
Patrys climbed 0.7 cents or 46.7 percent to 2.2 cents with 43.4 million shares traded.

ZELDA THERAPEUTICS

Zelda says it has a research agreement with the Children's Hospital of Philadelphia, Pennsylvania, to study the pharmacology of cannabinoids for autism.
Zelda said the research would focus on autism with an observational trial to better understand the efficacy of treatment in existing patients beginning in early 2018, with preliminary results anticipated within six months.
The company said the observational study was expected to describe cannabinoid disposition in paediatric patients and identify compounds that might demonstrate efficacy in the treatment of paediatric autism.
Zelda executive chairman Harry Karelis said the alliance had "the potential to deliver very robust clinical trial data" to show cannabinoids as a safe, effective and affordable option.
Zelda was up 0.1 cents or 1.1 percent to 9.2 cents with 7.9 million shares traded.

CSL

CSL says it has renewed its blood fractionation agreement with Australia's National Blood Authority for a nine year term.

A CSL spokesperson told Biotech Daily that CSL fractionated voluntary donated blood collected by the Australian Red Cross and returned it "free-of-charge based on clinical need as determined by appropriate clinical practice".

The spokesperson said there was a toll manufacturing charge, but patients received the 15 separate fractionated plasma products free-of-charge.

In its media release, CSL said the new agreement would replace an existing long-term agreement with the National Blood Authority due to expire on 31 December 2017, with the new agreement starting on January 1, 2018 and expiring on December 31, 2026, "subject to satisfactory performance against key measures and the satisfactory completion of a review against specified criteria to be completed during year five".

CSL Behring Australia and New Zealand general manager Loretta Croker said that the company welcomed "the opportunity to continue our longstanding commitment to provide plasma-derived therapies to treat people in Australia with serious medical conditions including diseases of the immune system, disorders of blood clotting, or people who have been severely injured".

"The National Fractionation Agreement for Australia provides the healthcare system access to a secure supply of high-quality plasma-derived therapies for the duration of its nine-year term," Ms Croker said.

CSL said it would supply a comprehensive portfolio of life-saving plasma products manufactured in its advanced manufacturing facility located at Broadmeadows in Melbourne's northern suburbs.

The company said that the source material for plasma-derived therapies was human plasma, or the liquid part of blood, donated by Australia's volunteer plasma donors, and collected by the Australian Red Cross Blood Service.

CSL said that with the National Blood Authority and the Red Cross Blood Service the agreement ensured that Australians could access a comprehensive range of domestically-sourced and manufactured plasma-derived therapies.

CSL fell 60 cents or 0.4 percent to $141.43 with 510,490 shares traded.

ITL HEALTH GROUP

ITL says its biomedical division has launched its Segment Sampler for laboratory blood sampling processes.

ITL said that the Segment Sampler facilitated "a safe, efficient process" for obtaining biological samples from a blood bag tubing segment while reducing the potential exposure of laboratory technicians to biologic products.

The company said there was a variety of applications for this product including obtaining a sample for use with point of release tests such as bacterial screening performed prior to a unit of platelets being transfused to a patient.

ITL said that other applications included obtaining samples from cellular therapy products such as cord blood.

The company said that its biomedical division had "a pipeline of multiple additional new products scheduled to reach the market in the current financial year".

ITL biomedical general manager Craig Wilson said the Segment Sampler "fills a real need in the market as we strive to make labs safer and more productive" and pre-launch customer feedback was "very positive".

ITL was untraded at 44 cents.

PRESCIENT THERAPEUTICS

Prescient says the US Food and Drug Administration has lifted the clinical hold on its phase II PTX-200 for HER2 negative breast cancer trial and recruitment can resume.
Prescient said it paused recruitment to all three of its PTX-200 trials following the death of the last of 29 patients in its phase Ib breast cancer trial, with its phase Ib/II trial for acute myeloid leukaemia resuming in September and the phase Ib trial for ovarian cancer resuming in November (BD: May 29, Sep 4, Nov 6, 2017).
Today, the company said it would resume recruitment of patients in the phase II part of the trial of PT-200 for breast cancer, but no one was available from the company to quantify the number of patients expected to be recruited to the trial.
Prescient said that it had met the FDA's requests for the trial, which included updating the risk mitigation plan to minimize risks around hepato-toxicity.
The company said that prior to the clinical hold, the breast cancer trial had met the phase Ib study pre-specified safety criteria, with "early encouraging signs of a positive effect from the preliminary efficacy analysis with five patients qualifying for phase II analysis".
Prescient chief executive officer Steven Yatomi-Clarke said the lifting of the hold was "a great result for Prescient and we are very pleased to now have all these clinical holds behind us".
Prescient was up 0.1 cents or 1.5 percent to 6.7 cents.

BIOXYNE

Bioxyne says preliminary data from its 61-patient trial of its probiotic Progastrim shows statistically significant differences for gastrointestinal, bowel health and antibiotic use.
Bioxyne said the double-blind, randomized, placebo-controlled trial studied the effect of one daily Progastrim capsule containing the probiotic PCC, or Lactobacillus fermentum VRI-003, with a minimum of two billion colony-forming units (CFUs), or viable cells, for six months on the microbiome composition, gut health and quality of life of healthy individuals.
The company said 47 subjects finished the trial with significant beneficial effects observed in reductions of bloating and gas and reduced antibiotic use during the study period.
Bioxyne said the statistical analysis was conducted by Datapharm Australia Pty Ltd.
The company said the number of days where patients did not experience any gastric symptoms showed the active group reported more days without symptoms than the placebo group ($p < 0.0001$).
Bioxyne said the PCC active group reported less bloating and gas than the placebo group ($p = 0.0036$ and $p < 0.0001$, respectively).
The company said that the active group reported less stomach rumbling than the placebo group ($p < 0.0001$), less other gastric symptoms ($p = 0.0020$), reduced other unspecified health issues ($p < 0.0001$) and participants in the active group reported reduced antibiotic use than the placebo group ($p < 0.0001$).
Bioxyne said women in the PCC group experienced greater improvements than men.
The company said there were no differences in the reporting of minor adverse events between the placebo and active PCC group, with no statistical difference for incidence rates of adverse events, suggesting that long-term consumption of PCC was safe.
Bioxyne science director Dr Peter French said the data "demonstrated the positive influence of Bioxyne's probiotic, PCC, to gastrointestinal health, and health in general".
"It is notable that a single capsule of PCC taken daily could produce several significant beneficial gut health effects," Dr French said.
The company said that the full analysis of the results was expected in early 2018.
Bioxyne fell 3.1 cents or 25.8 percent to 8.9 cents with 19.2 million shares traded.

ADMEDUS

Admedus says it has moved its financial year from June 30 to December 31, to align with "business sales cycles" and its annual general meeting will be delayed until May 2018.
Admedus said the change "more closely aligns Admedus' reporting period with its global business sales cycles, assisting with forecasting, cash flow management and investment decisions".
The company said that the Australian Securities and Investment Commission had been notified of this change and it would report on a six-month accounting period from July 1, 2017 to December 31, 2017.
Admedus said that its results would be published by the end of February 2018, with normal half and full-year reporting periods to begin on January 1, 2018.
The company said that its annual general meeting would be held in May 2018.
Admedus was up half a cent or 1.7 percent to 30 cents.

ORTHOCELL

Orthocell has requested a trading halt pending "an announcement regarding a capital raising".
Trading will resume on December 13, 2017 or on an earlier announcement.
Orthocell last traded at 38.5 cents.

OVENTUS MEDICAL

Oventus has requested a trading halt "pending an announcement regarding a proposed capital raising".
Trading will resume on August 4, 2016 or on an earlier announcement.
Oventus last traded at 70 cents.

MMJ PHYTOTECH

MMJ has requested a trading halt "pending an announcement regarding a material investment".
Trading will resume on December 13, 2017 or on an earlier announcement.
MMJ last traded at 41 cents.

THE HYDROPONICS COMPANY

Hydroponics says it will release 14,735,550 shares from escrow on December 23, 2017.
Hydroponics told Biotech Daily that following the release it would have 65,735,550 shares tradable from that date, with a further 250,000 shares in escrow until April 26, 2018 and 37,514,450 shares in escrow until May 4, 2019.
Hydroponics was up 3.5 cents or 4.6 percent to 79 cents.

REGENEUS

Regeneus says it has appointed the Japan-based Leo Lee as an independent non-executive director, effective immediately.

Regeneus said that Mr Lee had more than 20 years of experience in pharmaceutical innovation, commercialization, regulation and policy development, working in North America and Asia and spent the last 12 years in Japan.

The company said that Mr was currently the president of Merck Serono Japan and was previously Allergan Japan's president.

Regeneus chairman Dr Roger Aston said the Mr Lee's "skills, experience, network and knowledge of the Japanese market make him a valuable and strategic addition to the board particularly with our recent collaboration with AGC [Asahi Glass] in Japan and our focus on clinical licencing and development of Progenza for the Japanese regenerative medicine market".

Regeneus was up one cent or eight percent to 13.5 cents.