Biotech Daily

Monday November 9, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ATCOR, MEDICAL DEVELOPMENTS UP 12% - PRIMA DOWN 8%**

*** FEDERAL GOVERNMENT $630m FOR 800 NHMRC GRANTS**

*** EMA EXPANDS ADMEDUS CARDIOCEL TO WHOLE VALVE REPLACEMENT**

*** ARMARON BIO PHASE II TRIAL OF NP202 FOR CARDIAC RECOVERY**

*** NEUREN RAISES $6.3m FOR PAEDIATRIC RETT SYNDROME TRIAL**

*** IRELAND OKAYS MEDICAL DEVELOPMENTS PENTHROX, $900m ORDERS**

*** VIRALYTICS STORM TRIAL: 'CAVATAK HITS TUMOR, WELL TOLERATED'**

*** JOURNAL ARTICLE BACKS USCOM OVER CATHETER FOR CHILDREN**

*** IMMURON, ONE WAY LIVER WORK ON NASH DIAGNOSTIC**

*** ANTISENSE APPOINTS RESMED'S DR GARY PACE DIRECTOR**

*** ONCOSIL TO RELEASES 7.5m ESCROW SHARES**

*** PRANA BELOW $US1 NASDAQ NON-COMPLIANCE**

*** ALLAN GRAY REDUCES TO 10% OF PHOSPHAGENICS**

*** GOLDMAN SACHS ABOVE 5% OF NANOSONICS, YET AGAIN**

MARKET REPORT

The Australian stock market fell 1.83 percent on Monday November 9, 2015 with the ASX200 down 95.5 points to 5,119.5 points. Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and three were untraded.

Atcor and Medical Developments were equal best, both up 11.63 percent to 24 cents and $3.84, respectively, with 392,773 shares and 88,755 shares traded, respectively. Circadian and Pro Medicus climbed more than nine percent; Genetic Technologies was Up 7.4 percent; Neuren rose 6.7 percent; Ellex, Pharmaxis and Starpharma were up more than four percent; Actinogen, Biotron and Clinuvel were up more than three percent; Benitec and Tissue Therapies rose more than one percent; with Admedus and Psivida up more than one percent.

Prima led the falls, down 0.4 cents or 7.7 percent to 4.8 cents with 17.1 million shares traded. Compumedics lost 6.25 percent; Uscom fell 5.3 percent; Avita and Living Cell fell more than four percent; Bionomics, Cellmid, Nanosonics and Polynovo were down more than three percent; Antisense and Oncosil shed more than two percent; with Osprey down 1.75 percent.

FEDERAL GOVERNMENT

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

The Federal Government has announced $630 million for more than 800 National Health and Medical Research Council (NHMRC) grants.

The Federal Minister for Health Sussan Ley said that more than 2,000 researchers would share the grants for projects including obesity prevention; cancer genomics and hereditary diseases, drugs for crystal methamphetamine addiction, a treatment for drug-resistant depression, treatments for post-traumatic stress disorder and the impact shift-work has on pregnancy outcomes, with individual grant details available at: https://www.nhmrc.gov.au/grants-funding/outcomes-funding-rounds.

In 2014, the Federal Government provided $580 million for National Health and Medical Research Council grants, with $559 million in 2013, $652 million in 2012 and $763 million in 2011 (BD: Oct 20, 2011, Oct 19, 2012; Oct 23, 2013; Oct 17, 2014).

Ms Ley said the announcement includes $121.7 million for cancer research, $76.5 million for cardiovascular disease, $49.7 million for mental health research, $36.2 million for diabetes, $34.8 million for Aboriginal and Torres Strait Islander Health, $25.1 million for dementia research, $22.1 million for injury research, $16.1 million for obesity, $13.1 million for arthritis and osteoporosis and $6.9 million for asthma.

“Our research workforce is one of the strongest in the world and I have no doubt that through their expertise, talent and creativity, these researchers will make huge advances in improving human health,” Ms Ley said.

Ms Ley said that the Medical Research Future Fund would “identify and coordinate national health priorities, as well as continue to support individual research projects through the National Health and Medical Research Council”.

ADMEDUS

Admedus says the European Medicines Agency has granted a broader label indication for Cardiocel for valve and annular repair in Europe.

Admedus said that the expanded indication meant that Cardiocel was approved for use in the repair and reconstruction of heart valves including replacing the whole valve, in addition to congenital heart defects and was more in line with the US label.

The company said that the expanded indication was “a significant step in establishing Cardiocel as the regenerative tissue product of choice for repairing and reconstructing heart valves” and was part of the strategy to drive sales growth.

Admedus said that Cardiocel was used in more than 120 centres in Europe, the US, Canada, Hong Kong, Singapore and Malaysia and in Australia through access programs.

Admedus chief executive officer Lee Rodne said the label expansion was “important … and will help us to increase the use of Cardiocel in Europe, particularly in adult patients”.

Admedus said it was undertaking a post-approval clinical study with cardiac centres to further bolster the clinical data available for Cardiocel to demonstrate the benefits to patients in whole valve reconstructions over bio-prosthetic valve replacement.

The company said that it was working with partner Genpharm in the Middle East and Northern Africa for additional approvals as well as exploring new markets in Asia.

Admedus said that Cardiocel was launched in Europe at the end of 2013 and had been implanted in more than 3,000 patients and the label extension would enable surgeons to use it to repair congenital heart defects, heart valve repairs and augmentations, as well as whole heart valve reconstructions.

Admedus was up 0.1 cents or 1.6 percent to 6.4 cents with 4.75 million shares traded.

ARMARON BIO

Armaron Bio says it has begun a 120-patient, phase II trial of NP202 to reduce scarring following heart failure and improve cardiovascular function.

The private, Melbourne-based Armaron said the double-blinded, placebo-controlled, randomized trial in Australia, New Zealand and the US would evaluate NP202 which "actively reduces the scar tissue and prevents cardiac remodelling following heart failure" to show improvement in heart function 90 days after NP202 administration.

The company said it was looking at NP202 to treat other indications such as Alzheimer's disease, diabetic kidney failure and traumatic brain injury.

Armaron chief executive officer Dr Grant McLachlan told Biotech Daily that NP202 was an anti-apoptotic, or anti-programmed cell death, drug developed at the University of Melbourne and the Howard Florey Institute.

In a media release, Armaron said it was supported by Starfish Ventures and received funding from Astrazeneca's Medimmune Ventures.

The company said that about 54,000 Australians had a cardiac arrest each year, with the heart muscle becoming "scarred and too weak to pump blood around the body".

Armaron said that "while the majority of heart attack patients survive the initial trauma, around 50 percent of survivors die within five years of their heart attack from heart failure".

The company said that if successful, its drug could be given to patients following a heart attack, preventing the scarring that causes heart failure.

Armaron said the primary endpoint was the change from baseline in the heart's size and function, assessed by magnetic resonance imaging at 90-days, with results expected by July 2017.

Dr McLachlan said that heart failure killed "50 percent of patients within five years of diagnosis and results in more than one million hospitalisations in the US annually".

The Newcastle New South Wales-based John Hunter Hospital principal investigator Prof Andrew Boyle said the trial was "an important step in developing new treatments for this devastating condition, which affects so many heart attack patients".

"In laboratory studies, NP202 actively treats the cause of heart failure rather than simply managing blood pressure and clearing fluid," Prof Boyle said.

Armaron said that a phase I single ascending and multiple ascending dose trial showed that five doses of NP202 from 50mg to 1,600mg were safe and well tolerated and a cohort of eight subjects given two dose levels for 14 days showed the drug was safe and well tolerated up to 1,000mg/day.

NEUREN PHARMACEUTICALS

Neuren says that it expects to raise $6.3 million through the issue of 70,000,000 shares at 9.0 cents a share to accelerate development of trofinetide for Rett syndrome.

Neuren said the placement to sophisticated investors, led by the company's largest share-holder Lang Walker, followed a $1.37 million commitment from the International Rett Syndrome Foundation for its phase II paediatric trial (BD: Oct 13, 2015).

The company said the additional funding placed it "in a very strong position to accelerate the development of trofinetide for Rett syndrome" through to 2017 and activities planned for 2016 included the paediatric trial, pre-clinical safety studies to support a new drug application and completion of the optimization and scale-up of manufacturing.

The company said that investment in the pre-clinical and manufacturing activities for Rett syndrome would directly benefit the development of trofinetide for Fragile X syndrome, acute brain injury and other neurological disorders.

Neuren was up 0.6 cents or 6.7 percent to 9.5 cents with three million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says the Republic of Ireland's Health Products Regulatory Authority has approved its Penthrox inhaled analgesic for trauma and associated pain.
Medical Developments chief executive officer John Sharman said the approval gave its distribution partner in Ireland and the UK, Galen, the opportunity to sell Penthrox effective immediately.
"Galen is planning to launch Penthrox in December 2015 and we have received our first firm orders totaling almost $900,000," Mr Sharman said.
"We have commenced manufacturing and expect to deliver these first orders commencing in January 2016," Mr Sharman said.
Mr Sharman said that Galen had forecast orders for delivery by July 2016 totaling more than $1.3 million.
Medical Developments climbed 40 cents or 11.6 percent to $3.84.

VIRALYTICS

Viralytics says that high-dose Cavatak patients have shown evidence of successful tumor targeting and the drug is generally well-tolerated.
Viralytics said that the data from the phase I systemic treatment of resistant metastatic disease (Storm) trial of intravenous Cavatak, or Coxsackievirus A21 in advanced cancers was presented at the Society for the Immunotherapy of Cancer meeting in National Harbor, Maryland.
The company said that the phase I trial had administered multiple intravenous doses of Cavatak to patients with late-stage non-small cell lung cancer, hormone refractory prostate cancer, metastatic bladder cancer and late stage melanoma.
Viralytics said that initial results from the dose-escalation phase in the first 12 patients, including six patients in the third cohort administered the highest dose of Cavatak, showed that multiple infusions of Cavatak were generally well-tolerated with no grade 3 or higher Cavatak-related adverse events.
The company said there was evidence of successful tumor targeting in two melanoma patients in cohort 3, the highest dose, with Cavatak replication and Cavatak RNA evident in tumor biopsies and biopsies also showed the presence of immune cell infiltrates and notable levels of PD-L1 staining suggesting a potential benefit for Cavatak with an immune checkpoint blockade agent such as Merck and Co's Keutruda, or pembrolizumab.
The company said that a number of patients exhibited signs of possible tumor-specific secondary viral replication and several patients achieved a best overall response of stable disease, including one with a confirmed partial response.
Viralytics said that multi-dosing with single-agent Cavatak in cohort 3 of the Storm trial continued and the second stage of the trial, due to begin in 2016, would assess the intravenous delivery of Cavatak in combination with Keytruda in patients with advanced non-small cell lung or metastatic bladder cancer.
Viralytics said that its phase I Cavatak in non-muscle invasive bladder cancer (Canon) trial administered by catheter directly into the bladder showed that Cavatak was generally well-tolerated with no grade 2 or higher Cavatak-related adverse events.
The company said that evidence of targeting of tumor tissue, with viral replication and tumor cell death, was seen in patients following single or double administrations of Cavatak, as well as clinical activity with signs of viral replication and viral-induced tumor inflammation and a complete tumor response in one of the three patients in the highest dose cohort.
Viralytics was unchanged at 68 cents.

USCOM

Uscom says a double blinded, prospective, observational study confirms the accuracy of the Uscom 1A compared to invasive catheter measurements.
Uscom said that the study of 31 children aged nine months to 19 years was the first to validate the non-invasive Uscom 1A ultra-sonic cardiac output monitor as a replacement technology for the invasive pulmonary artery catheter in children.
The study entitled, 'Validation of an Ultrasound Cardiac Output Monitor as a Bedside Tool for Pediatric Patients' was published in the journal Pediatric Cardiology and an abstract was available at: http://www.ncbi.nlm.nih.gov/pubmed/26364291.
Uscom said the study was performed by researchers from the Children's Hospital, Los Angeles and the University of Southern California's Keck School of Medicine.
The abstract concluded: "We found that the estimation of [cardiac output] and by extension [systemic vascular resistance index] with Uscom is reliable against pulmonary artery catheter thermo-dilution in children with normal cardiac anatomy".
"Given the non-invasive nature of Uscom, speed of measurement, and relative ease of use, it may be useful as a bedside tool for pediatric patients," the abstract concluded.
Uscom said that the mean measures by each method differed by less than five percent, while the mean error was 11 percent "well inside the acceptable error which was determined a priori to be 30 percent".
The company said that the pulmonary artery catheter procedure required anaesthesia, and cardiac catheterisation could take up to two hours to perform and was associated with a significant risk of infection and death.
Uscom said that its monitor was entirely non-invasive and caused less distress to children than a simple blood pressure reading, taking five to 10 minutes per measure and was entirely safe.
The company said that the monitor was a recommended standard of care in the Pediatric Sepsis Guidelines for measurement of cardiovascular function and implementation of advanced haemo-dynamics.
Uscom executive chairman Prof Rob Phillips said the study "provides the evidence necessary for widespread adoption of the Uscom 1A in paediatric critical care medicine and cardiology and supports its replacement of the [pulmonary artery catheter] and other less accurate methods more generally".
Uscom fell one cent or 5.3 percent to 18 cents.

IMMURON

Immuron says it will collaborate with One Way Liver SL to develop a non-alcoholic steato-hepatitis (NASH) companion diagnostic for its drug IMM-124E.
Immuron said that the Derio, Spain-based One Way Liver, also known as Owl Metabolomics, would assist in the evaluation and validation of non-invasive markers for the NASH diagnostic.
The company said that samples from the 120 patients to be enrolled in its NASH phase II trial would be tested to assess the performance of the Owliver test and some would be subjected to full metabolomics analysis and if the results were promising, the companies would work on a companion diagnostic.
Immuron said the terms of the agreement were confidential.
Immuron chief executive officer Thomas Liquard said that "the only accepted diagnostic tool for NASH today is a liver biopsy, which is arguably not applicable in the clinical setting as a monitoring tool".
Immuron was unchanged at 45 cents.

ANTISENSE THERAPEUTICS

Antisense says it has appointed Resmed director Dr Gary Pace as a non-executive director.

Antisense said that Dr Pace had “a wealth of experience … [with] more than 40 years … in the development and commercialization of advanced technologies in biotechnology, pharmaceuticals, medical devices and the food industries”.

The company said that Dr Pace had held senior positions in small to large life sciences ventures and companies in Australia, the US and Europe and in 2003 was awarded a Centenary Medal by the Australian Government “for service to Australian society in research and development” and in 2011 was awarded Director of the Year (corporate governance) by the San Diego Directors Forum.

Antisense said that Dr Pace was currently a director of Resmed, Pacira Pharmaceuticals and Transition Therapeutics as well as several private companies and was previously a director of Peplin which was sold to Leo Pharmaceuticals in 2009.

The company said that Dr Pace held a Bachelor of Science from the University of New South Wales and a Doctorate of Philosophy from the Massachusetts Institute of Technology where he was a Fulbright fellow.

Antisense said that Dr Pace had authored or co-authored more than 50 research and review papers, had been awarded 24 patents and had held visiting academic positions at the Massachusetts Institute of Technology and the University of Queensland.

Antisense fell 0.2 cents or 2.6 percent to 7.5 cents.

ONCOSIL MEDICAL

Oncosil says that 7,500,000 shares held in voluntary escrow will be released on November 23, 2015.

Oncosil company secretary Tom Milicevic told Biotech Daily that following the release of the shares, the company would have 356,162,460 shares available for trading, with a number of employee share plan shares locked in escrow.

Oncosil fell half a cent or 2.8 percent to 17.5 cents with 1.8 million shares traded.

PRANA BIOTECHNOLOGY

Prana says it has been notified by the Nasdaq that it is non-compliant with the rule that listed securities maintain a minimum bid price of $US1.00 per share.

Prana said that notification had no effect at this time on the listing of its American depositary shares (ADSs) which would continue to trade under the symbol PRAN.

The company said that its ASX shares were in compliance with ASX listing requirements and were completely independent of the Nasdaq listing.

Prana said it would “actively monitor the bid price for its ADSs and will consider all available options to regain compliance with the … minimum bid price requirement”.

The company said it had 180 days, until May 2, 2016, to regain compliance with the minimum bid price requirement and if its closing bid was at least $US1.00 for at least 10 consecutive business days, Nasdaq would provide the company a written confirmation of compliance and the matter would be closed.

Prana said the in the event that it did not regain compliance, it might be eligible for an additional 180 calendar days' extension to regain compliance.

Prana said that if the Nasdaq concluded that it would not be able to cure the deficiency or if the company was otherwise not eligible, the ADSs would be subject to delisting.

Prana was unchanged at 11.5 cents.

PHOSPHAGENICS

Allan Gray says it has reduced its holding in Phosphagenics from 152,341,550 shares (12.07%) to 130,225,989 shares (10.32%).
Allan Gray, previously known as Orbis Investment Management, said that between November 3 and 5, 2015 it sold 22,115,561 shares for $408,759 or 1.85 cents a share.
Last year, Phosphagenics raised $16.3 million in a placement at eight cents a share and a further $3 million through a share plan (BD: Jul 11, Aug 5, 2014).
Phosphagenics was unchanged at 1.9 cents with 11.7 million shares traded.

NANOSONICS

The Delaware-based Goldman Sachs Group says that, yet again, it has become substantial in Nanosonics with 14,369,412 shares or 5.07 percent.
Goldman Sachs said that between July 14 and November 4, 2015 it acquired between 50 shares and 1,344,230 shares for no cost, with the single largest purchase 194,961 shares for $258,323 or $1.325 a share, which the company previously reported and on November 4, acquired 748,264 shares at no applicable cost.
Throughout October, Goldman Sachs has repeatedly increased above or reduced below the five percent substantial threshold in Nanosonics, primarily borrowing or returning shares “to the counterparty under a repurchase agreement” for no applicable consideration (BD: Oct 2, 5, 15, 16, 20, 23, 27, 28, Nov 5, 6, 2015).
Previously, under a counterparty agreement, Goldman Sachs returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australia, HSBC Custody Nominees Australia and the Bank of New York Mellon (BD: Apr 13, 2015).
Nanosonics fell 6.5 cents or 3.9 percent to $1.585.