Biotech Daily

Thursday October 18, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: PRANA UP 20%, CIRCADIAN DOWN 12%**

*** SPECIAL AUTHORIZATION FOR 1st ALLIED INFANT CARDIOCEL IMPLANT**

*** STARPHARMA VIVAGEL BACTERIAL VAGINOSIS TRIALS RECRUITED**

*** RAMACIOTTI FOUNDATIONS $1.6m FOR BIOMEDICAL RESEARCH**

*** BIONICHE IMMUNOCIDIN 'ALTERNATIVE TO CHEMOTHERAPY IN DOGS'**

*** FEDERAL COURT APPROVES ALCHEMIA-AUDEO DEMERGER**

*** FDA INDICATIONS CALL COULD BOOST RESONANCE FERRISCAN**

*** GENETIC TECHNOLOGIES, ONE LAMBDA PATENT AGREEMENT**

*** US PATENT FOR CALZADA POLYNOVO NOVOSORB**

*** PHYLOGICA AGM FOR NOTES, 6m EXECUTIVE BONUS OPTIONS**

MARKET REPORT

The Australian stock market was up 0.69 percent on Thursday October 18, 2012 with the S&P ASX 200 up 31.2 points to 4,559.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and five were untraded.

Prana was the best on no news, but following an overnight 18.9 percent rise on the Nasdaq, up five cents or 19.6 percent to 30.5 cents with 2.6 million shares traded, followed by Viralytics up 18.2 percent to 32.5 cents with 437,523 shares traded and Neuren up 10.7 percent to 3.1 cents with 9.4 million shares traded.

Optiscan climbed 9.8 percent; Cellmid was up 7.1 percent; Ellex climbed 5.9 percent; Anteo, Bionomics, Genera and Impedimed were up more than three percent; Pharmaxis and Starpharma rose more than two percent; Clinuvel, Living Cell and QRX were up more than one percent; with CSL and Sirtex up by less than one percent.

Circadian led the falls, down five cents or 11.9 percent to 37 cents with 1,300 shares traded. Genetic Technologies and Sunshine Heart lost more than eight percent; Phylogica fell 7.4 percent; Benitec was down 6.25 percent; Universal Biosensors shed 5.7 percent; Allied Health, Avita, Prima and Psivida were down more than three percent; Tissue Therapies shed 2.35 percent; with Acrux, Alchemia, Biota, and Mesoblast down more than one percent.

ALLIED HEALTHCARE GROUP

Allied Health says its Cardiocel tissue patch for congenital heart defects has been implanted in infants at Brisbane's Mater Hospital under a special authorization.
Allied said the Cardiocel implantation was the first use outside a clinical trial.
The company said the Australian Therapeutic Goods Administration last month authorized the use under an Authorised Prescriber Scheme, allowing the cardiothoracic surgeon to use the Cardiocel heart patches to treat patients prior to full marketing approval.
Mater Hospital surgeon Prof Tom Karl said Cardiocel was "expected to add significant long term value to our existing surgical practice of repairing [congenital heart defects] and is expected to allow our patients to live a normal life, free of implanted tissue related complications".
"The authorized prescriber approval provides an exciting opportunity for our patients to benefit from this new technology immediately," Prof Karl said.
Allied Health said that in 10 years of preclinical and clinical studies Cardiocel patches had shown no evidence of cytotoxicity or toxic cell damage, nor calcification at the implantation site for one to three years post-surgery.
Allied Health managing director Lee Rodne, said that Cardiocel provided a biocompatible scaffold for native tissue repair and retained tensile strength, thereby addressing key problems associated with existing tissue matrix products.
"The global medical community has been searching for tissue that doesn't cause the patient's own heart tissue to react negatively," Mr Rodne said.
Allied's regenerative medicine division chief executive officer Bob Atwill said Cardiocel was "an important new technology for the global market, and has a high potential of making a significant difference to [congenital heart defects] patients' lives".
"Other key Australian surgeons are in the final processes of becoming authorized for the use of Cardiocel via the Authorised Prescriber Scheme," Mr Atwill said.
Allied said that congenital heart defects were a major cause of death in infants and in Australia there were about eight cases per 1,000 live births.
Allied said it was seeking full TGA approval of Cardiocel and would lodge applications for US Food and Drug Administration approval by early 2013 and an application for a Conformité Européenne (CE) mark was underway.
Allied fell 0.1 cents or 3.85 percent to 2.5 cents with 3.6 million shares traded.

STARPHARMA

Starpharma says it has completed recruitment in its two US phase III trials investigating Vivagel as a treatment for bacterial vaginosis.
Starpharma said that the double-blind, phase III treatment trials were conducted across more than 30 international sites and recruited 250 patients in each trial trial.
The company said that trial results were expected to be available by early December 2012, following patient follow-up, data collection and the necessary statistical analyses.
Starpharma said that the studies were the subject of a formal agreement with FDA under the special protocol assessment program, which confirmed that the trial design, clinical endpoints and statistical analyses were acceptable for FDA approval once completed.
The company said that recruitment had also been completed for its phase II study for the prevention of bacterial vaginosis recurrence, with results expected early in 2013.
Starpharma said that a dialogue continued with potential licencing partners as do activities to support a new drug application and other regulatory submissions, with required manufacturing validation and scale up activities completed.
Starpharma was up four cents or 2.8 percent to $1.465.

RAMACIOTTI FOUNDATIONS

The Ramaciotti Foundations has provided $1.6 million in grants to 23 Australian biomedical researchers.

The Ramaciotti medal for excellence in biomedical research, which comes with a $50,000 grant, was awarded to the University of Sydney's Prof Kathryn North, who led the team that discovered a skeletal muscle gene, alpha-actinin-3 (ACTN3), linked to athletic muscle performance and function, dubbed 'the gene for speed'.

A Ramaciotti media release said that Prof North's research showed that although one in five Australians were deficient in alpha-actinin-3, no Olympic sprint athletes had ever been found deficient in the gene.

The media release said that Prof North hoped to use the discovery to unlock new neuromuscular genetic information, which would help children and adults prevent, isolate or better manage muscular diseases in the future.

A spokeswoman for the Ramaciotti Foundations said grants of between $61,000 and $75,000 had been awarded to 22 other medical researchers across Australia.

The Foundations said they were managed by Perpetual to support biomedical research through assistance to areas of research including molecular biology, genetics and immunology and assisting young researchers taking up new challenges in biomedical research.

The media release said the Ramaciotti Foundations were established in 1970 by Vera Ramaciotti with $6.7 million in funds. Since then, the charitable trusts have donated more than $52.5 million to biomedical research.

Perpetual's general manager of philanthropy Andrew Thomas said the winners of the awards and grants made an "outstanding contribution to biomedical research".

"Their work is a testament to the value of Australian-lead innovation," Mr Thomas said.

A detailed award list is at: http://www.perpetual.com.au/pdf/ramaciotti-grant-winners.pdf

BIONICHE LIFE SCIENCES

Bioniche says its Immunocidin canine oncology therapy is being launched at the Veterinary Cancer Society conference in Las Vegas, Nevada October 18-21, 2012.

Bioniche said Immunocidin was based on its mycobacterial cell wall technology, which is in phase III trials for human bladder cancer as Urocidin.

The company said that Immunocidin was indicated as an immunotherapy for the intratumoral treatment of mixed mammary tumor and mammary adenocarcinoma in dogs and had received regulatory approval in Canada and the US.

Bioniche said a survey of US veterinarians for the company showed that mammary carcinoma is the third most common cancer treated in the last 12 months by the respondents, with an average of 2.1 cases per month.

The company said that respondents reported an average of 19 cases of canine cancer each month, or about eight percent of their total canine patient base and about two-thirds of cancer cases were treated in-house.

Bioniche said that more than 18 percent of cases received some form of chemotherapy, either alone or in conjunction with surgery, but limitations were identified with the use of chemotherapy, including lack of capability of handling the drugs in the clinic, owner resistance and excessive cost.

The head of Bioniche Animal Health Andrew Grant said that there was "a tremendous opportunity for a product like Immunocidin that does not require special handling and can be used by veterinarians … either alone or in combination with other therapies".

Bioniche was untraded at 48 cents.

ALCHEMIA

Alchemia says that the Federal Court of Australia has approved the scheme of arrangement to demerge Audeo Oncology Inc.
Alchemia said that the Scheme would become effective once a copy of the Court order was lodged with the Australian Securities and Investments Commission today, October 18, 2012.
The company said that the scheme would only be implemented if the Audeo Oncology fundraising and initial public offering were completed by December 31, 2012.
Alchemia fell one cent or 1.7 percent to 58 cents.

RESONANCE HEALTH

Resonance says the US Food and Drug Administration has requested an expanded indication for use to include Ferriscan's specific role in the use of iron chelation therapy.
Resonance says that following the change, Ferriscan would be considered to be a companion diagnostic device, providing information that was considered essential for the safe and effective use of a corresponding therapeutic product.
The company said that the use of a companion diagnostic device would be stipulated in the instructions for use of both the Ferriscan diagnostic and the corresponding therapeutic product.
Resonance said that the approved indication for use of a medical device provided the scope for marketing and product claims and labelling.
The company said that Ferriscan was currently indicated for the measurement of liver iron concentration and expanding its indication for use was "an acknowledgement of the important role Ferriscan plays in clinical trials and in the clinical use of iron chelation therapies".
Resonance said the change had important potential implications for Ferriscan and could assist with gaining US reimbursement for Ferriscan; lead to a broader use of Ferriscan following the acknowledgment of its role in the management of patients with iron overload; and require any new competing medical device products seeking FDA approval to provide evidence to support claims of equivalence to all the Ferriscan indications for use".
The company said that iron chelation therapy was used for patients with iron overload from receiving regular blood transfusions and clinical trials were exploring its use in patients with non-transfusion dependent iron overload.
Resonance said that up to 25,000 people in the US received regular blood transfusions and required an annual assessment of their iron overload to manage their therapy and the number of non-transfusion dependent iron overload patients was be significantly higher.
Resonance said it provided Ferriscan to 40 US magnetic resonance imaging facilities and about 1,000 Ferriscans were provided to the US in the last 12 months.
Resonance was up half a cent or 55.6 percent to 1.4 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has executed a "covenant not to sue and release" agreement with the Canoga Park, California-based One Lambda Inc.
Genetic Technologies said that the commercial terms of the agreement were covered by confidentiality provisions and could not be disclosed.
The company said the agreement was reached as a result of its continuing patent monetization efforts in the US and other jurisdictions.
Genetic Technologies fell one cent or 8.7 percent to 10.5 cents.

CALZADA

Calzada wholly-owned subsidiary Polynovo says it has been allowed a third US patent in for its Novosorb portfolio, providing protection to 2027.
Calzada said the patent, entitled 'High modulus polyurethane and polyurethane/urea compositions' covered a broad range of biodegradable polymer compositions, particularly targeting medical device applications requiring high strength material such as vascular stents.
Calzada was up 0.2 cents or 4.4 percent to 4.7 cents.

PHYLOGICA

Phylogica shareholders will vote on the issue of 15,750 convertible notes and 6,000,000 options, exercisable at no cost, in lieu of bonuses to senior executives.
Phylogica said the notes would cost $100 each and convert at the lesser of 5.3 cents or the 30-day volume weighted average price to November 25, 2103.
The company said shareholders would vote on the right of directors to participate in the raising with 100 notes for chairman Dr Doug Wilson and 50 notes each for chief executive officer Dr Paul Watt, chief financial officer Nick Woolf and chief operating officer Dr Richard Hopkins.
Phylogica said that options exercisable at no cost would be issued to executives "in lieu of bonuses" and conditional on the share price reaching 10 cents by November 25. 2013.
The company said shareholders would vote to issue 2,250,000 options to Dr Watt, 1,500,000 options to Mr Woolf, 1,500,000 to Dr Hopkins and 750,000 to researcher Katrin Hoffmann.
Phylogica said shareholders would also vote on the remuneration report and the re-election of directors Jeremy Curnock Cook, Dr Watt and Mr Woolf.
The meeting will be held in the Seminar Room at the Telethon Institute for Child Health Research, 100 Roberts road, Subiaco, Western Australia, on November 22, 2012 at 11am (WST).
Phylogica fell 0.2 cents or 7.4 percent to 2.5 cents with 2.1 million shares traded.