Biotech Daily

Thursday March 6, 2014

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: VIRALYTICS UP 9%, CIRCADIAN DOWN 14%**

*** BIOTRON UP 314% ON 6-MONTH HEP C G-3 VIRAL CLEARANCE DATA**

*** PRIMA RECEIVES $1.6m FEDERAL R&D TAX REFUND**

*** FDA APPROVES CALZADA, POLYNOVO NOVOPORE WOUND TREATMENT**

*** VICTORIA OPENS UHS ELIZABETH BLACKBURN SCHOOL OF SCIENCES**

*** FEDERAL GOVERNMENT $31m FOR AUTISM RESEARCH**

*** IMMUNEXPRESS, DEBIOPHARM RAISE $6.7m**

*** PRANA: 'MIT STUDY BACKS PBT2 AMYLOID-BETA APPROACH'**

*** VIRALYTICS BEGINS UK PHASE I/II CAVATAK SOLID TUMOR TRIAL**

*** REGENEUS KVAX TUMOR VACCINE SAFE, EFFICACY IN RATS**

*** MJGD, BSMI TRUST, IRWIN, BIOA TRUST DILUTED IN BENITEC**

*** MESOBLAST APPOINTS EX-ROCHE CEO WILLIAM BURNS DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.01 percent on Thursday March 6, 2014 with the S&P ASX 200 down 0.3 points to 5,445.9 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, seven were unchanged and four were untraded. All Big Caps fell.

Viralytics was the best, up 2.5 cents or 8.6 percent to 31.5 cents with 136,023 shares traded. Universal Biosensors climbed 5.6 percent; Medical Developments was up four percent; Antisense, Sirtex and Starpharma were up three percent or more; Impedimed and Reva rose more than two percent; Admedus and Clinuvel were up more than one percent; with Psivida up by less than one percent.

Circadian led the falls, down three cents or 13.95 percent to 18.5 cents with 100,000 shares traded. Acrux and Benitec lost eight percent or more; Prima fell 6.25; Anteo was down 5.3 percent; Avita, Ellex and Pharmaxis fell four percent or more; both Atcor and Oncosil lost 3.7 percent; GI Dynamics, Patrys and Resmed shed more than two percent; CSL, Mesoblast, Neuren, Phosphagenics, Prana and QRX were down one percent or more; with Cochlear and Nanosonics down by less than one percent.

BIOTRON

Biotron climbed 314.4 percent to 31.5 cents on news that five hepatitis C genotype 3 patients in a trial of BIT225 for hepatitis C and HIV were clear of the virus at six months.
Last year, Biotron said that an interim analysis of virus levels in the treated patients indicated that all six genotype 3 subjects who completed 28 days of BIT225 therapy had undetectable levels of hepatitis C virus 12 weeks into the study (BD: Oct 25, 2013).
Today, Biotron managing director Dr Michelle Miller told Biotech Daily that, of the initial 12 patients who began the hepatitis C and HIV co-infection trial, five of the eight genotype 3 patients and one of four genotype 1 patients were clear of the virus at 24 weeks.
Dr Miller said that three genotype 3 and one of the genotype 1 patients dropped out due to intolerance of the interferon and ribavirin regime, with two genotype 1 patients not responding due to their IL-28 phenotype.
Biotron said that analysis of blood samples from the phase II trial patients "indicated that all of the [hepatitis C] genotype 3 patients completing treatment are virus free at the 24 week time point … [extending] previous data that showed patients had undetectable virus levels at 12 weeks".
The company said that response to treatment at this time point was "generally a good indication of final outcome at 48 weeks".
Biotron said that preliminary data from patients who had completed 48 weeks of treatment indicated that they remained virus-free at that time.
The company said that in the open label pilot study, 12 patients received interferon and ribavirin for seven days before commencing treatment with BIT225 and then received 300mg of BIT225 twice daily plus interferon and ribavirin for 28 days and then continued to take interferon and ribavirin for 48 weeks.
Dr Miller said that the 24-week data "further validates the efficacy of BIT225 as a potential new therapy for [hepatitis C] and, in particular, for this difficult to treat group of HIV [and hepatitis C] co-infected patients who typically have more serious [hepatitis C] infection and lower response rates to treatment with existing standard therapies," Dr Miller said.
Biotron said that in-vitro assays had shown that BIT225 had pan-genotypic activity and previous clinical trials of BIT225 focused on patients infected with the genotype 1 variant of the virus, which was the most common genotype in Western populations.
The company said that the data further extended the clinical data portfolio to include genotype 3, which was endemic in South-East Asia.
Biotron said that for hepatitis C, BIT225 targeted the p7 protein which was responsible for virus assembly and the drug also impacted on the assembly of the HIV virus and specifically targeted the virus in reservoir cells.
"No existing therapy works in this way," Biotron said.
Dr Miller said that both the HIV and hepatitis C viruses presented "substantial challenges and there is global demand for novel therapeutics".
Biotron climbed as much as 23.9 cents or 314.4 percent from last night 7.6 cents to close today up 9.4 cents or 123.7 percent at 17 cents with 41.9 million shares traded.

PRIMA BIOMED

Prima says it has received "approximately $1.6 million" from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Prima said the rebate related to research and development expenditure on its CVac ovarian cancer trials for the year to June 30, 2013
Prima fell 0.3 cents or6.25 percent to 4.5 cents with 11.1 million shares traded.

CALZADA, POLYNOVO BIOMATERIALS

Calzada says that the US Food and Drug Administration has granted its subsidiary Polynovo a 510(k) clearance for its Novopore topical negative pressure foam dressing.
Calzada said that Novopore, formerly known as Novosorb foam or Novosorb dressing, was intended for topical negative pressure therapy for chronic wounds such as pressure sores and the therapy was designed to remove wound exudate and promote granulation to regenerate the dermal tissue by applying vacuum through a dressing placed in the wound cavity.
The company said that the global topical negative pressure dressing market was estimated to be about $US400 million.
Calzada said that current topical negative pressure dressings previously raised concerns from the FDA relating to complications associated with infection as a result of foam fragments remaining in the wound and bleeding on removal of the dressing.
The company said that in a 2013 clinical trial Novopore demonstrated in its clinical trial completed last year that it had the potential to address the concerns raised by the FDA (BD: Apr 17, 2013).
Calzada said that Polynovo intended to form an alliance with a global partner to market and distribute Novopore in the US, while retaining manufacturing and supply rights.
The company said that in addition to the US 510 (k) approval, Polynovo was finalizing its Novopore Conformité Européenne (CE) mark application.
Polynovo chief executive officer Laurent Fossaert said the approval of “our first regulated product for our technology, [marks] a significant milestone for Polynovo and its Novosorb technology”.
“This 510 (k) will not only allow Polynovo to gain entry into the US market for Novopore but will also enhance the wider commercialization of our technology with potential future partners,” Mr Fossaert said.
Calzada was up one cent or 8.7 percent to 12.5 cents with 7.2 million shares traded.

VICTORIA GOVERNMENT, ELIZABETH BLACKBURN SCHOOL OF SCIENCES

Victoria’s Minister for Education Martin Dixon has opened the Elizabeth Blackburn School of Sciences for years 11 and 12 at University High School in the Parkville Precinct.
A Victoria Government media release said that the $7 million building would “deliver an academic program with strong connections to higher education pathways for Year 11 and 12 students”.
A University of Melbourne media release said that the school was a partnership between the University, University High School and the Victorian State Government and was located adjacent to the High School, at the Bio21 Institute site, opposite the University.
The University said that the dedicated sciences school was named after Prof Elizabeth Blackburn who, graduated from University High School and the University of Melbourne on her way to sharing the 2009 Nobel Prize for Physiology or Medicine for her work on DNA, chromosomes, telomeres and telomerase.
The media release said that the select-entry sub-school of University High would enroll up to 200 students in science, technology, engineering and mathematics, “with the aim of inspiring the next generation of scientists”.
“All students have access to scientist mentors, leading edge facilities within state of the art dedicated classrooms and exposure to an environment that inspires an interest in science,” the media release said.

FEDERAL GOVERNMENT

The Federal Minister for Industry Ian Macfarlane says the Cooperative Research Centre for Living with Autism Spectrum Disorders will receive $31 million over eight years.

A Federal Government media release said that the Autism Cooperative Research Centre (CRC) would support research to improve the understanding of autism and to assist people with autism and their families.

“The work of the CRC will focus on the full range of issues that affect people with autism,” Mr Macfarlane said.

“The CRC will work to build new links between science, industry and Government, with the ultimate goal of generating practical outcomes to improve the lives of people with autism and their families,” Mr Macfarlane said. “The research will include a focus on diagnosis, education, and supporting people with autism as they move into the workforce.”

The media release said that behavioral tools being developed by the CRC intended to ensure that at least 70 percent of autistic children were correctly diagnosed by the age of three and at least 50 percent by two years of age.

“Ensuring that children are diagnosed correctly at a young age can make a huge difference, not only to the child, but also their family,” Mr Macfarlane said.

The media release said that the Centre brought together occupational therapists, educators, biologists, psychologists, Governments, community groups and industry.

“This large and diverse group will take a whole-of-life approach and provide a range of benefits to people with autism from early age to adult life,” Mr Macfarlane said.

The media release said the CRC would develop a web portal with assistance programs and modules available for use by employers, health care professionals, educators, carers and family members.

More information about the Centre is at: www.crc.gov.au.

IMMUNEXPRESS

Immunexpress says a financing round, led by the Swiss-based Debiopharm Diagnostics SA has raised $US6 million ($A6.7 million) for its Septicyte sepsis diagnostic.

Immunexpress said the funds would bring one of the its late-stage sepsis diagnostic products to market for critical care patients.

The company said that the Septicyte technology was the basis for a range of products pipeline and quantified multiple specific molecular markers from the patient’s immune system for earlier diagnosis, detection, triage, screening, severity assessment and ultimately for better timing and targeting of drug and other therapies.

Immunexpress said that Sepsis was a challenge, with 1,400 patients dying each day and the leading non-coronary cause of death in intensive care units.

Debiopharm’s Thierry Mauvernay said that early detection of sepsis was critical and the two companies had been collaborating since June 2012.

“This revolutionary technology will utilize the early immune response to sepsis and potentially lead to more a targeted treatment approach for each patient, which may provide better outcomes for the patients who present with this life-threatening condition,” Mr Mauvernay said.

“We are impressed by their work and are confident that the future of sepsis management lies in the use of their innovative diagnostic technology,” Mr Mauvernay said.

Immunexpress chief executive officer Dr Roslyn Brandon said that the raising was “an important milestone for Immunexpress”.

Immunexpress is a private company founded in Brisbane as Athlomics and based in Seattle, Washington.

PRANA BIOTECHNOLOGY

Prana says that a landmark study demonstrates a dose dependent relationship between copper levels and oligomerisation of amyloid-beta peptide resulting in toxicity.

Prana said that its proof-of-concept metal protein attenuating compound, clioquinol, rescued the metal induced amyloid-beta toxicity, a finding consistent with the proposed mechanism of action of its PBT2 for Alzheimer's and Huntington.

The company said that the Massachusetts Institute of Technology Prof Susan Lindquist and colleagues described the development and validation of a novel yeast model for Alzheimer's-related beta-amyloid pathology, in which they screened 140,000 drugs, including clioquinol, for their ability to inhibit the toxicity resulting from amyloid-beta accumulation.

Co-author Dr Daniel Tardiff said the work in the yeast model "shows that clioquinol decreases the amount of amyloid-beta in the cells by 90 percent".

"That's a strong decrease and it's dose-dependent," Dr Tardiff said. "I've tested a lot of compounds before and I've never seen anything as dramatic."

The article, entitled 'Clioquinol promotes the degradation of metal-dependent amyloid-beta oligomers to restore endocytosis and ameliorate amyloid-beta toxicity' was published in the Proceedings of the National Academy of Sciences and an abstract is available at: http://www.pnas.org/content/early/2014/02/27/1402228111.short.

Prana said that PBT2 and clioquinol were from the same class of 8-hydroxyquinoline compounds and it selected PBT2 from its library of neurologically active 8-hydroxyquinolines based on its improved safety and efficacy profile compared to clioquinol.

Prana co-founder and chief scientific advisor Prof Rudy Tanzi, who is also a Harvard Medical School professor of neurology said the "very well crafted body of work from the Lindquist laboratory points to the intrinsic value of Prana's therapeutic strategy to intercede in the metal mediated toxicity of target aggregating proteins in neurodegeneration".

"However, unlike strategies which seek to merely reduce [amyloid-beta] levels, our strategy is to additionally disarm target proteins of metals, neutralize toxicity and redistribute metals to their correct neuronal compartments to restore neuronal function and neurotransmission," Prof Tanzi said.

Prana said the paper showed that analogues of clioquinol that were structurally modified not to contain its metal binding site were unable to rescue amyloid-beta toxicity, indicating that the toxic effect of beta-amyloid was most likely metal-mediated.

The company said that in-vitro, copper strongly promoted the formation of prefibrillar oligimeric amyloid-beta species and clioquinol strongly antagonized the oligomer-potentiating effects of copper.

Prana said that clioquinol was able to arrest toxicity in amyloid-beta-expressing yeast cells in a highly dose dependent manner and the rescue of amyloid-beta induced toxicity was replicated in the Caenorhabditis elegans worm model where amyloid-beta expressing glutamatergic neurons were preserved after treatment, compared to untreated controls.

The company said that the Lindquist laboratory previously showed that amyloid-beta/metal complexes caused defects in secretory/endosomal transport pathways and that defect was rescued by treatment with clioquinol.

Prana said that clioquinol increased the degradation of oligomeric species of amyloid-beta in the yeast model thus preventing its accumulation and resultant toxicity and the addition of equimolar concentrations of copper exhausted the ability of clioquinol to reduce amyloid-beta levels.

Prana fell 1.5 cents or 1.2 percent to $1.21 with 1.1 million shares traded.

VIRALYTICS

Viralytics says it has begun a 30-patient, UK phase I/II trial of intravenous Cavatak for late stage melanoma, prostate, lung or metastatic bladder cancer.
Viralytics said that the study would assess the multiple intravenous, or systemic, delivery of Cavatak for the diseases at three cancer centres with lead investigators the University of Surrey oncologist Prof Hardev Pandha, London's Royal Marsden Hospital's Prof Kevin Harrington and Leeds St James's University Hospital's Prof Alan Melcher
The company said that the first stage of the study would see Cavatak administered as a monotherapy in late stage cancer patients.
Viralytics said that in the second stage Cavatak would be administered with commonly used chemotherapeutics, such as docetaxel, carboplatin or paclitaxel, targeting only one cancer type, which would be identified as the most promising target from the first stage of the study.
Viralytics chief executive officer Dr Malcolm McColl said that "the commencement of the Storm clinical trial is another very significant milestone for Viralytics".
"Intravenous delivery of Cavatak has the potential to broaden the commercial application and benefit many more cancer patients," Dr McColl said.
Viralytics was up 2.5 cents or 8.6 percent to 31.5 cents.

REGENEUS

Regeneus says that safety and early efficacy data have been published for the Kvax cancer vaccine, for which it has a commercialization licence for veterinary applications.
Regeneus said that the Kvax vaccine used the removal of a tumor or biopsy as the source material for a personalized vaccine, to stimulate the immune system to see the cancer cells as foreign and help prevent further growth of the tumor as well as development of new tumors.
The company said it also had an option for all human applications.
Regeneus said that the data was published in an article entitled 'Streptavidin: A novel immunostimulant for the selection and delivery of autologous and syngeneic tumor vaccines' in Cancer Immunology Research.
The abstract is at: http://cancerimmunolres.aacrjournals.org/content/early/by/section.
Regeneus said that the technology was developed at Sydney's Royal North Shore Hospital Kolling Institute of Medical Research by Prof Ross Davey and Dr Chris Weir.
The company said that a pre-clinical rat glioma, or brain tumor, model showed that the vaccine led to remission rates of 30 percent to 60 percent and on re-challenge the animals did not get the disease, which indicated acquired immunity.
Regeneus said the paper also described the treatment of 25 dogs that had a range of advanced cancers from melanoma to bone cancer, in which there were no safety issues with the vaccine and the dogs "often survived longer than expected indicating that the vaccine can slow tumor growth and recurrence".
"The results from the work in rats is a major breakthrough," Dr Weir said. "The 9L glioma model is extremely aggressive and achieving the level of remission and immunity that we did, using a vaccine derived from tumors is significant and unique."
Regeneus said that in 2013 it was approved to commercialize the vaccine in the US through the US Department of Agriculture and it would set up a manufacturing site in the US and beginning a marketing trial with key opinion leaders in the US.
The company said that in the US cancer accounted for about half of the deaths of pets over 10 years of age, roughly the same rate as human.
Regeneus fell half a cent or 1.1 percent to 46.5 cents.

BENITEC BIOPHARMA

MJGD Nominees as trustee for BSMI Trust and Irwin Biotech Nominees as trustee for BIOA Trust say they have been diluted below five percent of Benitec.

Last year, the two Melbourne-based groups became substantial shareholders, each acquiring 4,769,091 shares or 6.47 percent of the company (BD: Jul 26, 2013).

The two groups own separate holdings.

Today Irwin Biotech Nominees as trustee for BIOA Trust said it held 4,379,686 shares and MJGD Nominees as trustee for BSMI Trust said it held 4,769,091 shares, but both had been diluted by the $31.5 million capital raising (BD: Feb 28, 2014).

Benitec fell 16 cents or eight percent to $1.85.

MESOBLAST

Mesoblast says it has appointed former of Roche Pharmaceuticals chief executive officer William Burns as a non-executive director, effective immediately.

Mesoblast said that Mr Burns was the chief executive officer of the pharmaceutical division of Swiss-based F Hoffman La Roche from 2005 to 2009 and a non-executive member of the Roche board from 2010 to 2014.

The company said that Mr Burns was a director of Genentech since 2002 and was a director of Chugai Pharmaceutical Co. and Shire plc.

Mesoblast said that Mr Burns was formerly the chairman of Okairos acquired in 2013 by Glaxosmithkline and Crucell, which was acquired in 2011 by Johnson & Johnson.

The company said that Mr Burns was also the chairman of the Wellcome Trust's Health Innovation Challenge Fund Funding Committee and was the European medical companies' representative on a British Government industry steering group.

Mesoblast fell eight cents or 1.4 percent to $5.69.