Biotech Daily

Tuesday December 15, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PSIVIDA UP 19%; GENETIC TECHNO DOWN 10%**

*** PHOSPHAGENICS PHOSPHA-E FAILS NESTLE METABOLIC TRIAL**

*** MERCK SERONO SPENDS $1.6bn ON R&D**

*** IMPEDIMED ASIA DISTRIBUTOR; US LEGAL ACTION; ESCROW SHARES**

*** HALCYGEN ASKS HOSPIRA TO TRANSFER PRODUCTS TO MAYNE**

*** FEDERAL GOVERNMENT SPENDS $50m ON BIONIC EYE RESEARCH**

*** BIOMD TESTS ADAPT TISSUE FOR BIOCOMPATIBLITY**

*** BIOPHARMICA'S CORTICAL DYNAMICS FINISHES MONITOR RESEARCH**

*** BLACKROCK TAKES 5.3% OF COCHLEAR**

*** FERMISCAN ASSETS UP FOR SALE; LEON CARR IN NSW COURT**

MARKET REPORT

The Australian stock market climbed 0.4 percent on Tuesday December 15, 2009 with the S&P ASX 200 up 19.5 points to 4673.5 points. Ten of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and four were untraded.

Psivida was best, up 68 cents or 18.8 percent to $4.29 with 16,487 shares traded, followed by Tissue Therapies up one cent or 7.7 percent to 14 cents with 816,823 shares traded.

LBT and Novogen climbed five percent or more; Chemgenex was up 3.1 percent to $1 with two million shares traded; Optiscan rose 2.5 percent; with Bionomics and Living Cell up more than one percent.

Genetic Technologies led the falls, down 0.4 cents or 10 percent to 3.6 cents with 60,000 shares traded, followed by Alchemia down 7.4 percent to 56.5 cents with 159,262 shares traded.

Phosphagenics lost 6.9 percent with 2.6 million shares traded; Benitec and Biota fell more than five percent; Cathrx was down 4.6 percent; Prima was down 3.45 percent; Circadian, Cochlear, Impedimed, QRX, Sirtex and Universal Biosensors shed more than two percent; with Clinuvel, Genera and Nanosonics down more than one percent.

PHOSPHAGENICS

Phosphagenics says Nestlé Nutrition will not commercialize Phospha-E following the failure of the compound to meet the primary end point of a phase II clinical trial.

Phosphagenics said 174 patients were enrolled for the 12 week double-blinded, randomized, placebo-controlled trial, which was conducted at five sites across Australia and 144 patients completed the trial in accordance with the protocols.

The company said the trial of orally administered Phospha-E as a treatment for heart disease and diabetes had four arms: placebo, Vitamin E, Phospha-E at 200IU and Phospha-E at 400IU.

(One international unit (1.0IU) of vitamin E is the biological equivalent of two-thirds of a milligram (0.667mg) of d-alpha-tocopherol.)

Phosphagenics said blood samples were taken at six-weeks and 12 weeks.

The end-points included safety and tolerability of Phospha-E in humans, the effects on the inflammatory biomarker, high sensitive C-reactive protein (hsCRP), and on plasma lipids.

Phosphagenics said the study was not powered to show statistical significance, except when very large differences between treatments were observed.

The company said that oral Phospha-E had a positive effect on smokers, including the lowering of hsCRP and increasing high density lipoproteins or “good cholesterol”.

Phosphagenics said that orally administered Phospha-E was safe and well tolerated in all patients and led to a statistically significant improvement in some heart disease and diabetes risk factors, particularly in smokers.

Phosphagenics said Phospha-E could lower triglycerides with a statistically significant reduction in mean blood triglyceride concentration in subjects taking Phospha-E when directly compared to patients administered normal Vitamin E.

The company said there was a statistically significant 16 percent reduction in mean hsCRP among patients who were smokers when compared to smokers who received the placebo treatment (a 16% reduction in hsCRP) and a statistically significant 8.6 percent increase in plasma high density lipoproteins (HDL) compared to placebo.

Phosphagenics said there was a statistically significant 6.7 percent increase in the large HDL-C sub fraction (HLP) when compared to placebo treatment and a statistically significant 5.9 percent decrease in blood triglyceride concentrations when directly compared to patients receiving the standard Vitamin E treatment.

Phosphagenics said that total cholesterol and LDL-C were not changed in any of the treatment arms.

Overall, these results indicate there was a statistical and biological improvement in the lipid profile in patients with metabolic syndrome following six weeks of treatment with Phospha-E at 400IU.

The improvement in lipid profile was less pronounced 12 weeks after commencement of treatment, with no statistical significant differences between any of the treatment groups being observed for the main end-points, the company said.

Phosphagenics chief executive officer Harry Rosen said the company’s core tocopheryl phosphate mixture (TPM) technology delivering insulin and oxycodone transdermally remained the primary focus of the company.

“Phospha-E remains an area of interest to the company, but as has always been the case, the focus of the company remains very much on our key areas of the development and commercialization of the TPM transdermal and topical delivery technology, which has successfully delivered insulin, oxycodone and many other actives into humans in trials conducted by the company,” Mr Rosen said.

Phosphagenics fell 0.5 cents or 6.9 percent to 6.7 cents with 2.6 million shares traded.

MERCK SERONO

Merck Serono says it invests more than 20 percent of its total revenues, or EUR1 billion ($A1.6 billion) each year, to discover and develop new therapies.
In a presentation and teleconference in Sydney, Merck Serono said it had 30 projects in clinical development including eight in clinical trials in Australia.
The company said it focused on unmet medical needs in oncology; neurodegenerative diseases such as multiple sclerosis and Parkinson's disease; autoimmune and inflammatory diseases such as rheumatology and osteoarthritis; fertility in which it said it was leading innovation with new embryology technologies and solutions to improve pregnancy rates; and endocrinology with research into growth hormone and targeted indications.
Merck Serono said among the compounds in phase III development were Impetreve (Cilengitide) the first in a new class of targeted anticancer therapies known as integrin inhibitors, currently being developed for glioblastoma multiforme, which was an aggressive brain cancer with high mortality and Stimuvax (L-BLP25) a therapeutic cancer vaccine using the body's own immune system to fight cancer and targeting an antigen expressed on many tumor types.
The company said it was collaborating with the Adelaide based Bionomics with access to new treatment targets for multiple sclerosis and autoimmune disease from Bionomics' Kv 1.3 program.
Merck Serono said the Bionomics collaboration was a new generation of treatments for inflammatory disorders, based on blockers of the Kv1.3 potassium ion channel.
The company said Kv1.3 was "a key regulator of the effector-memory T-Cells of the immune system that are key mediators of inflammatory diseases".

IMPEDIMED

Impedimed has appointed a distributor for China, Hong Kong, Taiwan and Macau, been served with a writ from a former US employee and has released shares from escrow.
Impedimed said it had appointed the Kowloon Hong Kong-based 3 Kings Holding a distributor for L-Dex products in Hong Kong, China, Taiwan and Macau.
Impedimed said that key personnel at 3 Kings Holding Limited had previously "held distinguished careers in the healthcare market in both Hong Kong and the People's Republic of China".
Impedimed chief executive officer Greg Brown said the appointment was "an important step for Impedimed in broadening our global presence … in this large, emerging market".
Separately, Impedimed said that with its wholly-owned subsidiary, Xitron Technologies Inc it had been served with a US civil action by James R Matthie, a former employee and founder of Xitron, relating to an agreement made by Xitron in 2001.
Impedimed chairman Mel Bridges told Biotech Daily that the company acquired Xitron, primarily for one patent on bioimpedance in 2007 and Mr Matthie had already departed the company.
The company said the claims made by Mr Matthie were without merit and that it was "in a strong position to defend the action successfully and intends to do so vigorously".
Impedimed said the legal expenses and management resources to defend the action would not impact on its business plan or its milestone targets.
Impedimed also announced the release of 304,348 escrowed shares, taking the total number of shares available for trading to 109,025,028 shares.
There are no further restricted shares other than employee performance shares.
Impedimed fell two cents or 2.4 percent to 82 cents.

HALCYGEN PHARMACEUTICALS

Halcygen has provided notice to Hospira Inc to transfer the marketing and distribution of products sold in Australia and Asia to Mayne Pharma International.
Halcygen merged with Mayne Pharma on November 2, 2009 (BD: Sep 25 Oct 28, 2009).
Halcygen said a suite of products including Doryx, Eryc, Magnoplasm and Astrix were sold to wholesalers by Hospira on behalf of Halcygen under the transitional services agreement between the two companies.
Under the same agreement Halcygen has the right to take up this activity on providing 60 days notice to Hospira.
Halcygen said the transfer of marketing and distribution activities to Halcygen would contribute to its earnings before interest taxation depreciation and amortization.
Halcycen chief executive officer Dr Roger Aston said the company was “very pleased to have progressed and be in a position to take on the task of marketing and distribution in Australia”.
“Halcygen was expecting to undertake the transfer of the marketing and distribution rights during the first 12 months following the acquisition of Mayne Pharma International,” Dr Aston said.
Halcygen said it would use the three main pharmaceutical wholesalers in Australia to achieve nationwide distribution to hospitals and pharmacies.
Distribution in Asia will be either through direct sales or through suitable marketing and distribution partners, the company said.
The company said the financial benefits of the transfer of marketing and distribution activities would begin in the second quarter of 2010.
Halcygen was up three cents or 5.4 percent to 59 cents.

FEDERAL GOVERNMENT

The Minister for Innovation Senator Kim Carr says two research teams will share $50 million to develop a bionic eye.
“The Australian Government’s investment will help us to give and restore sight to thousands of people around the world,” Senator Carr said.
A Government media release said $42 million would go to the Universities of Melbourne, New South Wales, Western Sydney and the Australian National University with collaborators including the National Information and Communications Technology Centre of Excellence, the Bionic Ear Institution and the Centre for Eye Research Australia.
Monash University and the Alfred Hospital will receive $8 million, the media release said.
“Both research teams submitted leading edge, innovative bionic eye concepts that include significant collaboration and show an exceptional ability to deliver health and economic benefits,” Senator Carr said.
“Team one will utilize a technology that implants a device in the rear of the eye, the retina, to enable vision to blind patients suffering from degenerative retinal conditions,” Senator Carr said.
“The second team aims to develop a device that is implanted directly on the region of the brain that processes vision signals, the visual cortex. This will provide treatment for progressive blindness,” he said.
The Government said funding was being awarded under the Australian Research Council’s research in bionic vision science and technology initiative, developed in response to the Australia 2020 Summit.
For more information, visit http://www.arc.gov.au/ncgp/sri/bionic_eye.htm.

BIOMD

Biomd says biocompatibility testing of its Adapt biomaterial has begun at the Ohio-based North American Science Associates (Namsa) testing facility.

Biomd said Namsa was the world's leading medical device contract research organization specializing in the safety and evaluation of medical devices.

The testing will give the necessary biocompatibility certification for its biomaterial patch products and will be used as an integral part of the regulatory submissions to the US Food and Drug Administration, Australian Therapeutic Goods Administration and for Conformitée Européenne late in 2010.

The company said that testing of the Adapt biomaterial involved a series of 21 tests, covering sensitization, cytotoxicity, bacterial and activation assays and systemic toxicity and were scheduled to be completed by August 2010.

During the testing the company said it would be assembling the technical dossier for the Adapt biomaterial, including the clinical evidence from small animal studies and the recently completed human clinical trial on heart deformities in South Africa (BD: Feb 19, Jul 16, Nov 9, 2009).

Biomd said it would complete its quality assurance program and be preparing a conformity assessment for the biomaterial that will form the basis of the regulatory submissions.

Biomd was untraded at 4.1 cents.

BIOPHARMICA, CORTICAL DYNAMICS

Biopharmica subsidiary Cortical Dynamics has completed grant-funded research on its brain monitoring system for anaesthesia.

Biopharmica chairman David Breeze said that following the spin-out, his company owned 3.6 percent of Cortical Dynamics but Biopharmica shareholders owned about 62 percent of the company.

Biopharmica said the 2007 National Health and Medical Research Council grant was for 'Commercial testing of a physiologically based theory of oscillatory brain electrical activity in anaesthesia monitoring'.

The company said the grant enabled further commercial development and testing of the physiologically-based anaesthesia monitoring process which monitors brain electrical activity and was administered through Swinburne University under Prof David Liley.

Biopharmica said Cortical Dynamics was developing the depth of anaesthesia monitoring system for use during major surgery and the core technology was based on real time analysis of the patients electroencephalogram using a proprietary algorithm based on a mathematically and physiologically detailed understanding of the brain's rhythmic electrical activity.

Biopharmica said the research enabled substantial improvements in the performance of the Brain Anaesthesia Response (BAR) monitor including a modified sensor layout with improved performance and sensitivity, as well as an upgrade of the data acquisition module to enable a greater resilience to the effects of noise and artefact in clinical monitoring.

The company said the hardware developments translated into significant improvements in the ability of the BAR monitor to detect a wide range of anaesthetic drug effects.

Biopharmica said the work concluded "the most important components of the system development and integration of the BAR monitor … and will allow a full suite of testing and calibration trials to occur prior to the monitor's full production and distribution".

Biopharmica was up one cent or 6.7 percent to 16 cents.

COCHLEAR

Blackrock Investment Management has become a substantial shareholder in Cochlear with a holding of 2,993,832 shares or 5.3 percent.

Cochlear fell $1.52 or 2.3 percent to $64.33.

FERMISCAN

Fermiscan's administrator Woodgate & Co's Giles Geoffrey Woodgate says the closing date for the sale of assets is January 6, 2009.

Mr Woodgate said the administrator's report to creditors dated December 1, 2009 was available from www.woodgate.com.au (BD: Nov 18, 2009).

Mr Woodgate said he had provided memoranda of information to interested parties for the purchase of the intellectual property, plant, equipment and business undertaking of Fermiscan Holdings, Fermiscan Pty Ltd, Fermiscan Australia and Fiberscan Pty Ltd.

A further announcement shall follow in the event that an offer to purchase the assets is accepted, Mr Woodgate said.

Separately, former Fermiscan director and major shareholder Leon Phillip Carr appeared in the New South Wales Supreme Court today.

The hearing before Justice Robert McDougall in the Equity Division was the second of two judgments involving Resource Equities Limited.

No details were available at the time of publication.